requirements specified by a particular foreign buyer.

If labeled to meet foreign labeling requirements, such packaged products cannot be sold in the United States. Pursuant to § 205.306, shipping containers and bills of lading for these products would have to be marked ''for export only'' to assure that the product was not distributed domestically. We are providing this exception to labeling requirements for the convenience of exporters only. If the foreign country or buyer does not require different product labeling, domestic product which has been produced, certified, and labeled pursuant to these regulations may be shipped without the statement, ''for export only,'' on the containers and bills of lading.

Organic product produced in another country for export to the United States may be certified to the requirements of this regulation or to an approved foreign organic certification program that has been recognized as equivalent to the requirements of the NOP. Such products must be labeled pursuant to the requirements of this subpart.

(3) *Product composition.* Under new § 205.301, Product Composition, we have clarified the composition of organic and nonorganic ingredients in products covered in the four labeling categories. All ingredients labeled as ''organic'' in the ingredient statement of the product package must be produced and handled pursuant to these requirements. No substances prohibited on the National List in subpart G and no production or handling practices prohibited in § 205.301(e) may be used in the production or handling of any ingredient labeled as ''organic.'' Regulations covering the production and handling of nonorganic ingredients varies with the labeling category. The higher the percentage of a product's organic composition, the more restrictive the production and handling requirements of the nonorganic ingredients in the product. These requirements are found under § 205.301 and explained above under Proposal Description.

(4) *Prohibited practices.* Section 205.301(e) lists seven production and handling practices that are prohibited from being used to produce whole products or product ingredients that would be labeled as ''organic'' under the NOP. Some of these prohibited practices appear for the first time in this proposal, and others were specified in the first proposal and were supported by all those who addressed them in their comments.

The first proposal prohibited organic labeling of a product or ingredient produced using water that does not meet requirements of the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*). We have not included that provision in this proposal because potable water is required in other FDA and FSIS processing regulations and does not need to be repeated as a requirement in this regulation.

The first three practices (use of excluded methods, sewage sludge, and irradiation) are discussed elsewhere in this proposal and are added as prohibited practices in this labeling section for consistency purposes.

Only processing aids and substances on the National List in subpart G of this regulation may be used in the production and handling of 95 percent-plus organic products and 50–95 percent organic products and in any ingredient labeled as organic on a product package.

The first proposal prohibited use of sulfites, nitrates, and nitrites in production or processing of organic products or ingredients. We have amended the wording of this provision to clarify that a handler cannot add any sulfites, nitrates, and nitrites to a product and still label the finished product or ingredient as ''organic.'' We make this clarification because these substances are found naturally in many substances and may appear naturally in potable water used in processing.

The last two processing practices that would prohibit an ''organic'' label appeared in separate sections of the first proposal and are included in this proposal in § 205.301(e)(6) and (e)(7). The first is that products and organic ingredients assembled using organic or nonorganic forms of the same ingredient or component ingredients—depending on availability of the organic ingredients—cannot be labeled as ''organic when available'' or a similar phrase. Similarly, products and organic ingredients assembled using both organic and nonorganic forms of the same ingredient or component ingredients cannot be labeled as organic if that ingredient is identified as organic on the ingredient statement and included in the percentage of organic content on the information panel.

(5) *Calculating organic content.* Because labeling requirements are based on the amount of organic ingredients in a product, we have added new section 205.302, which addresses the calculation of organic percentages. Provisions in this new section were not included in the first proposal. While this should be a simple mathematical procedure, the section proposes certain guidelines for calculating and labeling organic percentages.

Only one percentage figure for total organic ingredients will be shown on a package. The percentage of individual organic ingredients will not be displayed.

An organic product may be constituted completely of organic liquid products. Therefore, this proposal adds the phrase, ''or fluid volume,'' in several places in the proposal when referring to liquid products and ingredients. For ingredients in liquid form that are reconstituted with water from a concentrate, the calculation would be based on a single-strength solution of the liquid concentrate. For products that may contain both dry and liquid organic ingredients, the percentage calculation would be based on the combined weight of the organic ingredients, including the weight of the liquid ingredients, minus water and salt.

(6) *Labeling of nonretail containers.* We have added new § 205.306, covering labeling of nonretail containers—those used only for shipping and storage of agricultural products labeled as organic or containing organic ingredients. While the same containers are commonly used for both shipping and storage, the first proposal did not reference storage containers or specify labeling requirements for those containers. These provisions are proposed only for products labeled as ''100 percent organic,'' ''organic,'' and ''made with organic (specified ingredients).'' Some may believe that use of the USDA Seal on a shipping container of products ''made with organic (specified ingredients)'' may be inconsistent with other labeling provisions prohibiting display of the Seal on consumer packages of those products. However, in the case of shipping and storage containers, the display of seals is not intended for marketing purposes but would be used for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These provisions will not apply to shipping and storage containers of products containing less than 50 percent organic ingredients.

(7) *Retail Food Establishments.* The extent of the regulatory authority of this regulation has been the subject of intense discussions in comments received, NOSB deliberations, and AMS discussions. Commenters claimed that it makes no sense to regulate and certify the production and handling of organic product but not require certification and regulate retail food establishments where some fresh foods containing organic ingredients are processed and

assembled and where they can become adulterated or misrepresented to the consuming public.

Retail food establishments that market organic product, whether produced in-store, in a corporate commissary, or by others, will be subject to the labeling provisions of this subpart as that labeling applies to: (1) Point-of-purchase, in-store displays describing the organic nature of the product; and (2) other market information and media advertising regarding the product being marketed at the retail food establishment. Food retail establishments must describe the product in in-store retail displays, market information, and media advertising that is consistent with the organic content of the finished product. Any labeling of a product that is inconsistent with the percentage of organic content of the product will be considered a violation of truth in labeling and/or truth in advertising regulations of FDA and the FTC. Multiingredient products which are described as organic product in retail displays and market information must be assembled by a certified manufacturing facility, pursuant to the Applicability subpart of this regulation.

Packaged organic products, organic fresh produce, and organic bulk bin food items must be described in point-of-purchase displays, pricing information, and consumer information in terms consistent with the organic content of the product. For instance, an in-store retail display would describe an 87 percent organic product by specifying the percentage of organic content of the product and identifying the organic ingredients in the ingredient statement, as may be required by FDA. The market information for such a product must not, for instance, label the product as ''organic'' or ''100 percent organic.'' This would be a violation of truth in labeling and advertising regulations of FDA and FTC. The USDA Seal and the seal of the certifying agent may be displayed at retail sales and in market information on products certified as containing 95 percent or more organic content. Multiingredient products containing 50–95 percent organic ingredients may display the seal or logo of the certifying agent of the organic handling operation.

We believe these labeling practices will help assure appropriate representation of bulk organic products at retail sale and will encourage handlers to use more organic ingredients.

Products containing less than 50 percent organic ingredients at the point of retail sale may not be identified in any way as ''organic'' or containing organic ingredients. In addition, the USDA Seal and seal, logo, or other identifying mark of the certifying agent is prohibited from being used in retail displays and market information.

(8) *Change in calculating the $5,000 exemption.* We are proposing a change in calculating the $5,000 exemption for producers and handlers. The $5,000 annual exemption will be calculated on sales of organically produced product and not on all agricultural products marketed by the exempt producer or handler, as provided in the first proposal. This exemption means that qualifying exempt organic producers and handlers may annually sell up to $5,000 of organically produced products and not be certified as an organic operation under this regulation. The exemption could apply to a large, conventional agricultural operation that also has a small amount of acreage designated for organic production—the products of which, for example, is sold at a roadside stand. Any sale of other, nonorganic products will not count against the $5,000 sales total. The labeling and market information requirements for organic products produced by such exempt operations are specified in § 205.309 of this regulation.

Subpart E—Certification

This subpart sets forth the requirements for a national program to certify production and handling operations as certified organic production or handling operations. The certification process proposed in this subpart will be carried out by accredited certifying agents.

Proposal Description

General Requirements. Production and handling operations seeking to receive or maintain organic certification must comply with the Act and applicable organic production and handling regulations. Such operations must establish, implement, and annually update an organic production or handling system plan that is submitted to an accredited certifying agent. They must permit on-site inspections by the certifying agent with complete access to the production or handling operation, including noncertified areas and structures.

As discussed in Subpart B, certified operations must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' sufficient to demonstrate compliance with the Act and regulations. Records applicable to the organic operation must be maintained for not less than 5 years beyond their creation. Authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent must be allowed access to the operation's records during normal business hours. Access to the operation's records will be for the purpose of reviewing and copying the records to determine compliance with the Act and regulations.

Certified operations are required to immediately notify the certifying agent concerning any application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of the organic operation. They must also immediately notify the certifying agent concerning any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and regulations.

Certification Process. To obtain certification, a producer or handler must submit a request for certification to an accredited certifying agent. The request must contain descriptive information about the applicant's business, an organic production and handling system plan, information concerning any previous business applications for certification, and any other information necessary to determine compliance with the Act.

Applicants for certification and certified operations must submit the applicable fees charged by the certifying agent. An applicant may withdraw its application at anytime. An applicant who withdraws its application will be liable for the costs of services provided up to the time of withdrawal of the application.

The certifying agent will decide whether to accept the applicant's application for certification. Certifying agents may decline to accept an application for certification but may not decline to accept an application on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Upon acceptance of an application for certification, a certifying agent will review the application to ensure completeness and to determine whether the applicant appears to comply or may be able to comply with the applicable production or handling regulations. As part of its review, the certifying agent will verify that an applicant has submitted documentation to support the correction of any deficiencies identified in a previously received notification of noncompliance. The certifying agent

will also review any available U.S. Department of Agriculture (USDA) data on production and handling operations for information concerning the applicant.

We anticipate using data collected from certifying agents to establish and maintain a password-protected Internet database only available to accredited certifying agents and USDA. This database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use this Internet database during their review of an application for certification. This data will not be available to the general public because much of the data would involve ongoing compliance issues inappropriate for release prior to a final determination.

After a complete review of the application, the certifying agent will communicate its findings to the applicant. If the review of the application reveals that the applicant may be in compliance with the applicable production or handling regulations, the certifying agent will schedule an on-site inspection of the applicant's operation to determine whether the applicant qualifies for certification. The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements for certification.

The certifying agent will conduct an initial on-site inspection of each production unit, facility, and site included in the applicant's operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by the International Organization for Standardization Guide 10011–1, ''Guidelines for auditing quality systems—Part 1: Auditing'' (ISO Guide 10011–1).[1] The certifying agent will use the on-site inspection in determining whether to approve the request for certification and to verify the operation's compliance or capability to comply with the Act and regulations. Certifying agents will conduct on-site inspections when the applicant or an authorized representative of the applicant who is knowledgeable about the operation is present. An on-site inspection must also be conducted when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable production or handling regulations can be observed.

The on-site inspection must verify that the information provided to the certifying agent accurately reflects the practices used or to be used by the applicant or certified operation and that prohibited substances have not been and are not being applied to the operation. Certifying agents may use the collection and testing of soil; water; waste; plant tissue; and plant, animal, and processed products samples as tools in accomplishing this verification.

The inspector will conduct an exit interview with an authorized representative of the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The main purpose of this exit interview is to present the inspection observations to those in charge of the firm in such a manner so as to ensure they clearly understand the results of the inspection. The firm is not required to volunteer any information during the exit interview but would be required to respond to questions or requests for additional information. The inspector will raise and discuss during the exit interview any known issues of concern, taking into account their perceived significance. As a general rule, the inspector will not make recommendations for improvements to the operation during the exit interview. However, the certifying agent will have the discretion to decide the extent to which an inspector may discuss any compliance issue.

Notification of Approval. A certifying agent will review the on-site inspection report, the results of any analyses for substances, and any additional information provided by the applicant within a reasonable time after completion of the initial on-site inspection. The certifying agent will approve certification upon making two determinations: (1) That the applicant's operation, including its organic system plan and all procedures and activities, is in compliance with the Act and regulations; and (2) that the applicant is able to conduct operations in accordance with its organic systems plan.

Upon determining the applicant's compliance and ability to comply, the agent will approve certification and issue a ''certificate of organic operation.'' The approval may include restrictions regarding minor deficiencies that would not prevent certification as a condition of continued certification. A certificate of organic operation will specify the name and address of the certified operation; the effective date of certification; the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and the name, address, and telephone number of the certifying agent. Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

Denial of Certification. Should the certifying agent determine that the applicant is not able to comply or is not in compliance with the act, the certifying agent will issue a written notification of noncompliance to the applicant. Applicants who receive a notification of noncompliance may correct the deficiencies and submit, by the date specified, a description of correction and supporting documentation to the certifying agent. As an alternative, the applicant may submit a new application to another certifying agent, along with the notification of noncompliance and a description of correction of the deficiencies and supporting documentation. Applicants may also submit, by the date specified, written information to the certifying agent to rebut the noncompliance described in the notification of noncompliance. When a noncompliance cannot be corrected, a notification of noncompliance and a ''notification of denial of certification'' may be combined in one notification.

The certifying agent will evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal. If necessary, the certifying agent will conduct a followup on-site inspection of the applicant's operation. When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, the certifying agent will approve certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue the applicant a written notice of denial of certification. The certifying agent will also issue a written notice of denial of certification when an applicant fails to respond to the notification of noncompliance. The

[1] ISO Guide 10011–1 is available for viewing at USDA–AMS, Transportation and Marketing Programs, Room 2945—South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212–642–4900; Facsimile: 212–398–0023.

notice of denial of certification will state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal.

An applicant who has received a notification of noncompliance or notice of denial of certification may apply for certification again at any time with any certifying agent. When the applicant submits a new application to a different certifying agent, the application must include a copy of the notification of noncompliance or notice of denial of certification. The application must also include a description of the actions taken, with supporting documentation, to correct the deficiencies noted in the notification of noncompliance. When a certifying agent receives such an application, the certifying agent will treat the application as a new application and begin a new application process.

A certifying agent has limited authority to deny certification without first issuing a notification of noncompliance. This authority may be exercised when the certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented its operation or its compliance with the requirements for certification.

Continuation of Certification. Each year, the certified operation must update its organic production or handling system plan and submit the updated information to the certifying agent to continue certification. The updated organic system plan must include a summary statement, supported by documentation, detailing deviations from, changes to, modifications to, or other amendments to the previous year's organic system plan. The updated organic system plan must also include additions to or deletions from the previous year's organic system plan, intended to be undertaken in the coming year. The certified operation must update the descriptive information about its business and other information as deemed necessary by the certifying agent to determine compliance with the Act and regulations.

Following receipt of the certified operation's updated information, the certifying agent will arrange and conduct an on-site inspection of the certified operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by ISO Guide 10011–1. Upon completion of the inspection and a review of updated information, the certifying agent will determine whether the operation continues to comply with the Act and regulations. If the certifying agent determines that the operation is in compliance, certification will continue. If any of the information specified on the certificate of organic operation has changed, the certifying agent will issue an updated certificate of organic operation. If the certifying agent finds that the operation is not complying with the Act and regulations, a written notification of noncompliance will be issued as described in § 205.662.

In addition to annual inspections, a certifying agent may conduct additional on-site inspections of certified operations to determine compliance with the Act and regulations. The Administrator or State program's governing State official may also require that additional inspections be performed by the certifying agent to determine compliance with the Act and regulations. Additional inspections may be announced or unannounced and would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The policies and procedures regarding additional inspections, including how the costs of such inspections are handled, would be the responsibility of each certifying agent. Misuse of such authority would be subject to review by the Department during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations could file complaints with the Department at any time should they believe a certifying agent abuses its authority to perform additional inspections.

Certification After Suspension or Revocation of Certifying Agent's Accreditation. When the Administrator revokes or suspends a certifying agent's accreditation, affected certified operations will need to make application for certification with another accredited certifying agent. The certification of the production or handling operation remains in effect during this transfer of the certification. The certified production or handling operation may seek certification by any qualified certifying agent accredited by the Administrator. To minimize the burden of obtaining the new certification, the Administrator will oversee transfer of the original certifying agent's file on the certified operation to the operation's new certifying agent.

Upon initiation of suspension or revocation of a certifying agent's accreditation, or upon suspension or revocation of a certifying agent's accreditation, the Administrator may initiate proceedings to suspend or revoke the certification of operations certified by the certifying agent. The Administrator's decision to suspend or revoke a producer's or handler's certification in light of the loss of its certifying agent's accreditation would be made on a case-by-case basis. Actions such as fraud, bribery, or collusion by the certifying agent, which cause the Administrator to believe that the certifying agent's clients do not meet the standards of the Act or these regulations, might require the immediate initiation of procedures to suspend or revoke certification from some or all of its client base. Removal of accreditation, regardless of the reason, in no way affects the appeals rights of the certifying agent's clients. Further, a certified operation's certification will remain in effect pending the final resolution of any proceeding to suspend or revoke its certification.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's contractual obligations. As noted elsewhere in this proposed rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by the Department. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act.

Certification—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *On-site Inspection Requirements.* We have amended the general requirements provision concerning on-site inspections. The first proposal required production and handling operations to permit an annual on-site

inspection by the certifying agent. A few commenters suggested that the term, ''inspection,'' be made plural and that the section citations be amended to include the section on additional inspections. The section on additional inspections addressed the certifying agent's authority to perform on-site inspections in addition to the annual on-site inspection.

The commenters believe that ''inspection'' should apply to all situations when on-site inspections must be or could be performed, including the initial site inspection for a new certification as well as, for instance, compliance inspections. Commenters believe that these changes are needed to assure access to the certified operation and that an applicant's agreement to permit any and all necessary on-site inspections should be clearly stated as a general requirement for certification.

We had intended for the general requirements provision concerning on-site inspections to include all instances in which an on-site inspection might be appropriate. Accordingly, we have amended the requirement by replacing the phrase, ''an annual on-site inspection,'' with the phrase, ''on-site inspections.'' This terminology would cover initial, annual, and additional inspections needed for certification, continuation of certification, and to determine whether the operation is in compliance with program requirements. To ensure complete access to the production or handling operation for the purpose of conducting on-site inspections and determining compliance with the requirements of the National Organic Program (NOP), we have added a requirement that the operation permit complete access to the production or handling operation, including noncertified areas and structures. The general requirements provision on on-site inspections is found at § 205.400(c).

(2) *Providing Access to Records.* We have clarified the meaning of providing access to the records that the certified operation must maintain by adding ''during normal business hours for review and copying'' to the regulation. The first proposal required that certified organic operations maintain records for not less than 5 years from the date of their creation. It also required the certified operation to allow authorized representatives of the Secretary, the applicable governing State official, and the certifying agent access to such records to determine compliance with the Act and regulations.

Several comments were received regarding these recordkeeping requirements. Most of these comments were received from organic producer organizations and certifying agents. A few commenters questioned the necessity of maintaining records for 5 years, requested a different period for different records, and requested clarification on the meaning of providing access. Section 6511(d) of the Act requires organic production or handling operations to maintain records for 5 years. Accordingly, we have made no change to the retention period in this proposal. The clarification on the meaning of providing access to records is found at § 205.400(d).

(3) *Notification of Drift.* We have amended the requirement that production and handling operations immediately notify the certifying agent concerning any application of a prohibited substance by adding the phrase, ''including drift.'' A few commenters suggested adding a requirement that the certified operation notify the certifying agent when an organically certified field is contaminated by drift. They stated that drift is the most common reason for prohibiting the organic label on otherwise organically produced product.

We agree that the certified operation should immediately report any drift of a prohibited substance onto an organic field to its certifying agent. Accordingly, § 205.400(f)(1) provides that an applicant seeking to receive or maintain organic certification must immediately notify the certifying agent concerning any application, including drift, of a prohibited substance. This provision applies to new applicants as well as to ongoing certified operations. Contamination by drift could occur during the time period between application for and approval of certification. Accordingly, an applicant for certification would be required to notify the certifying agent of any contact with a prohibited substance.

(4) *Applicant Requirements.* We have added the requirement that applicants for certification include other information necessary to determine compliance with the Act and regulations. Commenters suggested that the we add a provision to the application regulations requiring applicants for certification to submit other information deemed necessary by the certifying agent. They stated that this authority is needed to assure that applicants are fully cooperative and responsive throughout the certification process.

We believe the requested authority would be helpful to certifying agents. However, we believe the authority for certifying agents to request other information they deem necessary must be qualified by the requirement that the information be necessary to determine compliance with the Act and regulations. Accordingly, we have provided certifying agents with the authority to request other information necessary to determine compliance with the Act and regulations. This addition is found at § 205.401(d).

(5) *Requirement for Notification of Noncompliance.* We have replaced the first proposal's section on ''preliminary evaluation of an applicant for certification'' with a new section on ''review of application.'' We have revised the section to clarify that certifying agents will issue notices of noncompliance only after the initial on-site inspection of an applicant's operations. We also allow applicants to voluntarily withdraw their application for certification at any time.

This change was in response to comments on the first proposal's requirement that applicants for certification report, to the certifying agent with whom they have applied, the receipt of a notice of noncompliance received from another certifying agent. A State organic growers association stated that this requirement places a stigma on applicants who, for example, applied for certification before the operation was ready to meet all requirements for certification. This commenter suggested that notification of previous denial only be required after an applicant has been denied certification. The commenter went on to say that, if the language in the original proposal is maintained, there should be a time limit of within the past 3 or 5 years of denial. Another commenter suggested that certifying agents have the option of recommending that noncompliant applicants withdraw their applications rather than be denied certification. As an alternative, one of the commenters suggested that denial of certification to an unprepared applicant should not have to be reported on a subsequent application to another certifying agent unless the first noncompliance notice led to a denial of certification.

We continue to believe that it is in the best interest of the program and consumers to require applicants to report the receipt of notices of noncompliance and denial of certification to any certifying agent to whom they make application. However, we also believe that operations should not be unnecessarily stigmatized because they applied for certification before the operation was ready to meet all requirements for certification.

Accordingly, this proposal requires that an applicant report the receipt of a notice of noncompliance or denial of certification to any certifying agent to whom application is made but allows applicants to voluntarily withdraw their application at any time.

An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance would not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial would not be issued a notice of certification denial.

(6) *Residue Testing.* We have revised the verification of information provisions to provide that the on-site inspection of an operation must verify that prohibited substances have not been and are not being applied to the operation. Verification would be through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

Comments from certifying agents suggested adding a provision that would allow a certifying agent to collect samples of substances from the operation for residue testing. They stated that such testing is necessary to detect unreported use or accumulation of prohibited substances. Section 6506(a)(6) of the Act requires periodic residue testing by certifying agents of products produced by certified organic operations. It is our intent that collection of samples for residue testing may be conducted as part of initial on-site inspections, as well as during on-site inspections of certified organic operations. The inspector could collect samples of soil; water; waste; seeds; plant tissues; and plant, animal, and processed products. Collection of such samples would be at the discretion of the certifying agent. To maintain the integrity of the inspection process, it is necessary that the certifying agent or inspector collect such samples first hand, rather than receive the samples from the applicant. We have made the requested addition at § 205.403(c)(3).

(7) *Postinspection Conference Requirements.* We have amended the postinspection conference requirements. We have changed all references to ''postinspection conference'' to ''exit interview.'' We have removed the requirement that the inspector discuss his or her observations regarding the operation's compliance or ability to comply with the Act and regulations. This requirement has been replaced with the requirement that the inspector confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector can use the exit interview to request any additional information necessary to establish eligibility for certification. Finally, this amendment requires the inspector to raise and discuss during the exit interview any known issues of concern.

Certifying agents commented that it would be inappropriate for an inspector to discuss observations and possible violations of compliance at an exit interview. They stated that requiring exit interviews places the inspector in the position of providing observations and feedback to the applicant before the inspector is able to confer with the certifying agent. Some certifying agents expressed concern that exit interviews could result in inspectors providing false or misleading information to the applicant. Some commenters requested that exit interviews be held only for the purpose of checking the accuracy and completeness of inspector observations made and the information obtained during the inspection. Other commenters requested that the exit interviews requirement be removed from these regulations.

We believe that qualified inspectors should be capable of competently discussing an applicant's compliance or ability to comply with these regulations. However, we also believe that a certifying agent should have the opportunity to decide whether to allow its inspectors to discuss issues of compliance at an exit interview. Accordingly, we have amended the exit interview requirements as noted above. These amended requirements are found at § 205.403(d).

(8) *Additional Inspections.* We have added a new provision that additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State program's governing State official. This change was made in response to commenters who requested the addition of a requirement that certifying agents conduct unannounced site visits in addition to the initial and annual inspections. We believe that unannounced on-site inspections are appropriate and valuable in both monitoring and investigating compliance with the Act and regulations. The requested addition is found at § 205.403(a)(2)(iii).

(9) *Requirements for Written Inspection Reports.* We have removed the requirement that the certifying agent require an inspector to prepare and submit to the certifying agent, within 30 days of completing an inspection, a written report that describes the inspector's observations and assessments of the inspected operation's compliance or ability to comply with the Act and regulations. A variety of comments, pro and con, were received on this requirement. Certifying agents questioned whether the 30-day timeframe was reasonable. Other commenters suggested that, rather than specifying a time period, the section should stress the need for timely reporting. A commenter suggested that an inspector's observations and assessments on the inspected operation include the inspector's recommendations on approval of certification. Other commenters stated that the requirement amounted to micro management of a certifying agent's business. This latter group of commenters believe that the setting of a time period for inspector reporting involves a policy matter that should be determined by the certifying agent. We agree with the commenters who stated that setting deadlines for the filing of inspection reports is an internal policy matter better left to certifying agents.

We believe that policies and procedures regarding inspector reporting are the purview of the certifying agent. Certifying agents would be expected to develop and implement inspector reporting requirements for on-site inspections internal to their own operations. Such policies and procedures and a certifying agent's performance in making timely certification decisions would be subject to review during accreditation and reaccreditation of the certifying agent. Accordingly, we have removed the provision.

Removal of this requirement does not eliminate the need for a written on-site inspection report or the importance of timely inspection reporting by an inspector to the certifying agent. Certifying agents are expected to make timely decisions regarding whether to certify an applicant and whether a certified operation is in compliance with the Act and regulations. Applicants with complaints regarding timeliness of service could forward their complaints to the Administrator.

(10) *Responsibilities of Certifier in the Application Process.* We have replaced the list of requirements to be reviewed by a certifying agent in determining an applicant's eligibility for certification with a general statement on determination of eligibility. Commenters requested the addition of a provision requiring certifying agents to verify implementation of the organic system plan. We agree that an on-site

inspection of an ongoing operation must include assessment of the operation's application of its organic system plan. Because an on-site inspection of a new applicant's operation would be conducted at a time when the operation can demonstrate its organic capabilities, the operation must be able to show that it is satisfactorily carrying out its organic system plan.

It was our intent that certifying agents would verify implementation of the applicant's organic system plan during the certifying agent's review of the on-site inspection report and application. However, our list of requirements to be reviewed by a certifying agent in determining an applicant's eligibility for certification did not specifically reference verification of implementation of the organic system plan. We have decided to replace the list of requirements to be reviewed with a general statement on determination of eligibility. This statement provides: ''If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall approve certification.'' We believe this general statement, in combination with the requirement that the certifying agent review the application, the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant, adequately addresses the commenters' concerns. This revision to the approval of certification requirements is found at § 205.404(a).

(11) *Information Included on the Certificate of Organic Operation.* We have amended the regulations specifying what information must be included on a certificate of organic operation. Comments received from organic operations, certifying agents, and consumers recommended that certifying agents provide additional information on certificates of organic operation. Specifically, they recommended that all certificates include: (1) The certifying agent's name and address; (2) an expiration date; (3) the physical location of certified operations, including separate fields and facilities; (4) the name of the certified operation's contact person responsible for compliance with program requirements; (5) the name and address of the certified operation; and (6) the crops and products certified. The commenters believe such information, especially a date on which the certificate expires, to be vital to assuring accountability and compliance with the program.

We believe it would be beneficial to persons with concerns regarding a certified production or handling operation to have ready access to information concerning the name, address, and telephone number of the certifying agent. Further, because the certificate of organic operation would be an official document of the certifying agent, it would be appropriate for this information to appear on every certificate. Accordingly, we have added the name, address, and telephone number of the certifying agent to the information which must be included on every certificate. This addition is found at § 205.404(b)(4).

We disagree with the commenters who requested that certificates of organic operation display an expiration date. We believe annual expiration of a certificate would place an unnecessary burden on certifying agents and certified operations. Annual expiration of certificates is also inconsistent with the fact that an operation's certification does not expire. In fact, once an operation is certified as an organic operation, its certification remains in effect until surrendered by the certified operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator. All certified operations are required to annually update their organic system plan. If the updated plan causes information on the certificate to be incorrect, the certifying agent will issue a new certificate with the correct information. This provides a mechanism for ensuring that certificates are updated as necessary on an annual bases. We have not included the recommended addition in this proposal.

For clarification, we have added § 205.404(c). This section provides that once certified a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

We disagree with the commenters who requested that certificates display the physical location of certified operations, including separate fields and facilities, and the name of the certified operation's contact person responsible for compliance with program requirements. We believe that the location of a certified operation's fields and facilities has no relationship to the operation's status as a certified organic operation. Therefore, such information should only be made available with the written consent of the certified operation. The name of the certified operation's contact person would be releasable information. We believe, however, that such detail is unnecessarily burdensome to the certifying agent and will only serve to clutter the certificate. By requiring the name, address, and telephone number of the certifying agent, as noted above, the certificate would provide interested persons with a contact for obtaining releasable information concerning the certified operation. Further, the certifying agent is the first line of compliance under this program and, as such, is the person to whom all questions and concerns should be addressed about certified operations.

We agree with the commenters who requested that certificates display the name and address of the certified operation because such information is potentially beneficial to consumers. Accordingly, we have added the name and address of the certified operation to the information which must be included on every certificate. This addition is found at § 205.404(b)(1).

The first proposal required that the certificate list the category(ies) and type(s) of products produced by the certified operation. Commenters were apparently confused about the meaning of category(ies) and type(s) of products. We have, therefore, revised the requirement to provide that a certificate of organic operation would specify the categories of organic operation, including, crops, wild crops, livestock, or processed products produced by the certified operation. This revision is found at § 205.404(b)(3).

(12) *Certifiers Authority to Deny Certification.* We have added authority for certifying agents to deny certification to applicants who do not meet the requirements for certification. The first proposal required certifying agents to forward their recommendations for denial of certification to the Administrator. Commenters stated that authority for denial of certification should rest with the certifying agents. They also contended that referral to the Administrator for denial of certification establishes a bureaucratic process, which would create unnecessary delays to the denial process and increased cost to applicants. Many commenters suggested the appeals process is sufficient to protect the interests of the Secretary.

We have determined that it is reasonable to authorize certifying agents to deny certification. Denial by the certifying agent would provide the applicant with a more timely decision on its eligibility for certification. A more timely decision would provide an

earlier opportunity for applicants to appeal a denial of certification. Authority for certifying agents to deny certification to applicants who do not meet the requirements for certification is found at section 205.405.

This proposal requires certifying agents to evaluate the applicant's corrective actions taken and supporting documentation or written rebuttal submitted in response to a notification of noncompliance. Certifying agents are authorized to perform on-site inspections to verify corrections to deficiencies or statements contained in a rebuttal, if necessary, to assure full compliance with the certification requirements. The certifying agent will issue the applicant a written notice of denial of certification if the corrective action or rebuttal is not sufficient for the applicant to qualify for certification.

We believe the denial of certification provisions should clearly state an applicant's options and rights upon receiving a notice of denial of certification. Accordingly, § 205.405(c)(1)(ii) provides that a notice of denial of certification must state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal. An applicant who has received a written notice of denial of certification may apply for certification again at any time with any certifying agent, may request mediation to resolve a dispute with the certifying agent, or may file an appeal with the Administrator as outlined in § 205.663 for mediation and § 205.681 for appeals. Applicants subject to an approved State program would seek mediation or appeal in accordance with the rules of the approved State program.

(13) *Willful Misrepresentations or False Statements by Applicants.* We have included authority for certifying agents to deny certification if the agent has reason to believe that the applicant has willfully made a false statement or otherwise purposefully misrepresented its operation or compliance with the certification requirements. Such false statements would, in most cases, be verified during an on-site inspection. This authority was provided to certifying agents in the first proposal relative to certified operations. The first proposal, however, did not reference an applicant's willful making of a false statement or otherwise purposefully misrepresenting its operation or compliance with the certification requirements. Certifying agents commented that applicants for certification also may make false statements or misrepresent facts. They suggested that the regulations reflect a certifying agent's authority in such cases. We agree with the commenters and have added § 205.405(f). This section authorizes denial of certification without first issuing a notification of noncompliance when the certifying agent has reason to believe that the applicant has willfully made a false statement or otherwise purposefully misrepresented its operation or compliance with the certification requirements.

Certification—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Timeliness of Applicant's Notification to Certifiers.* A commenter suggested that ''immediately'' in the requirement that production and handling operations immediately notify the certifying agent concerning any application of a prohibited substance be replaced with ''within 2 days.'' No justification was given for the recommended change, and the change has not been made. ''Immediately notify'' means that the applicant or certified operation must at once notify its certifying agent upon learning that a prohibited substance has come in contact with any portion of its operation or production. The certifying agent will evaluate the circumstances surrounding the event and decide whether the certified operation acted within the intent of this requirement. This requirement is found at § 205.400(f)(1).

(2) *Notification of Changes to Certifying Agent.* Commenters questioned how the certified operation would know what changes in its certified operation or any portion of its operation would require reporting to its certifier. Certified operations are responsible for being familiar with the requirements of the Act and these regulations. Further, they have an obligation to contact their certifying agent when they have questions regarding compliance with this program. As a rule, certified operations should contact their certifying agent whenever the change is not covered under their approved organic system plan. The requirement that a certified operation notify its certifying agent concerning any change in its certified operation that may affect its compliance with the Act and regulations is found at § 205.400(f)(2).

(3) *Tests for Soil Fertility and Irrigation Water.* Certifying agents suggested that applicants for certification be required to submit test results for soil fertility and irrigation water quality to prove compliance with the NOP. We recognize that increasing soil fertility through organic production practices is a goal of the organic industry. However, soil fertility will not qualify or disqualify an applicant for organic certification. An applicant who has independently had such tests conducted may, but is not required to, include them with the application. While the Act requires that handlers only use in their products water that meets all Safe Drinking Water Act requirements, no similar requirements are placed on producers and the water they use to irrigate their crops. For these reasons, we are not requiring applicants for certification to submit soil fertility or irrigation water quality test results.

(4) *Timeliness of On-site Inspection.* The first proposal required a certifying agent to conduct an initial on-site inspection within a reasonable time following a favorable preliminary evaluation of an application for certification. Several commenters asked what constitutes reasonable time between submission of an application and an on-site inspection. Others stated that, when determining what constitutes reasonable time, consideration should be given to factors such as when the application was submitted relative to when activities demonstrating compliance can be observed and when the inspection can be scheduled to assure the presence of the applicant.

We stated in the first proposal that we did not specify a time within which an inspection must be conducted because the time would vary according to when the application was submitted and the type of operation to be inspected. Timely service will be in the best interest of certifying agents since applicants may forward complaints regarding service to the Administrator. Such complaints could have an impact on a certifying agent's reaccreditation or continued accreditation. Further, our original position is consistent with those commenters requesting flexibility in determining what constitutes reasonable time. Accordingly, we have made no changes in this proposal regarding what constitutes reasonable time. This requirement is found at § 205.403(b).

(5) *Additional On-site Inspections.* Some organic associations asked what would trigger a decision to conduct an additional on-site inspection. Commenters expressed the concern that certifying agents could conduct additional, unneeded inspections at the expense of operators who would have to pay the costs of the inspections. Other commenters asked who would pay for the additional on-site inspections. Some certifying agents suggested that guidelines need to be established under

which additional inspections must be conducted. A certifying agent suggested that additional inspections could be conducted based on the inspector's observations, the certifier's recommendation, and, possibly, third-party complaints.

The authority for on-site inspections is necessary for monitoring and compliance purposes at the discretion of the certifying agent, the Administrator, or a State program's governing State official. Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The on-site inspection would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

We believe policies and procedures regarding additional inspections, including how the costs of such inspections are handled, are the responsibility of each certifying agent. Misuse of such authority would be subject to review by the Department during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations could file complaints with the Department at any time should they believe a certifying agent abuses its authority to perform additional inspections. Accordingly, we have made no changes in this proposal based on these comments.

(6) *Annual Renewal of Certification.* Commenters requested annual renewal of certification rather than updates to a continuing certification program. Other commenters requested that the notice of certification have an ending date or be issued for an established period of time. An industry association commented that the proposed continuation of certification regulations requires a certified operation to annually certify that it is complying with the Act and these regulations. This commenter stated that the proposed continuation of certification procedures changes the process of recertification to one more closely resembling self-certification. Another industry association stated that certification until surrendered by the certified operation or suspended or revoked would make the assurance of compliance extremely difficult, if not impossible. This commenter further stated that certifying agents will be unable to effectively monitor applicants or gain needed information. This commenter recommended that renewal paperwork include the items specified in the continuation of certification regulations but that certifying agents use their own discretion as to the forms and information needed. Similarly, a certifying agent commented that certification must be renewed with an application on an annual basis and that no operation can be certified for life. This commenter recommended requiring a yearly application and other documentation deemed necessary by the certifying agent.

We disagree with the commenters. We prefer continuous certification due to the very real possibility that the renewal process might not always be completed before expiration of the certification period. Expiration of the certification period would result in termination of the operation's certification. Even a short period of interruption in an operation's organic status could have severe economic ramifications. Further, we believe that a regular schedule of expiration of certification is unnecessary inasmuch as all certified operations are required to annually update their organic system plan and submit any changes to their certifying agent. Accordingly, this proposal retains the provision for continuous certification.

(7) *Timing of On-site Inspections.* A State certifying agent and an industry organization stated that requiring an on-site inspection after receipt of the renewal application is not consistent with current practice. The State certifying agent stated that it moved the renewal date to January 1 of each year to make the renewal process less burdensome to its certified producers. This commenter went on to say that the annual inspection conducted during the appropriate growing or processing season is used to evaluate the organic operation in the renewal process. The State certifying agent further stated that an additional inspection at renewal time would not be useful if it was not an appropriate time to observe production practices at the organic operation. Both commenters requested elimination of the requirement that the certifying agent arrange and conduct an on-site inspection following receipt of the operation's annual submission of information. These commenters also requested that a determination of noncompliance be based on on-site inspections conducted during the previous certification year and a review of the information annually submitted by the certified operation.

We disagree with the commenters. Certifying agents are required to schedule on-site inspections for a time when land, facilities, and activities that demonstrate the operation's compliance or capability to comply with the applicable production or handling provisions of the NOP may be observed. Accordingly, the initial certification must have followed an on-site inspection performed when the operation was able to demonstrate its compliance or capability to comply. The certified operation, therefore, should be fulfilling its annual continuation of certification obligations at a time when it can demonstrate its compliance with the Act and regulations. The commenters' recommendations are not accepted.

Certification—Additional Provisions

Upon further review of the certification provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Requirements for Business Information.* We have revised the business information required of all applicants for certification as an organic operation. First, the application must include the name of the person who completed the application. Certifying agents will use this information when following up on information within the application. Second, we have removed the requirement that the application include the names of personnel responsible for maintaining compliance with the Act and regulations. We believe this information is unnecessary since the person responsible for overseeing compliance is the certifying agent. Third, we have added the requirement that when the applicant is a corporation, the application must include the name, address, and telephone number of the person authorized to act on the applicant's behalf. Fourth, we have removed the requirement that the applicant for certification submit a statement of compliance. We have also removed the ''Statement of Compliance'' section which required the submission of a statement of compliance with the application for certification. We have removed this requirement because we have determined that it creates an unnecessary burden upon applicants for certification. Section 205.400(a) requires that a person seeking to receive or maintain organic certification must comply with the Act and applicable production and handling regulations. Accordingly, it is unnecessary to require a separate document through which the applicant for certification agrees to comply with the Act and regulations. The requirements for the submission of business information with the request for certification are found at § 205.401(b).

(2) *Disclosure of Previous Applications.* The first proposal

required that the request for certification include the name(s) of any organic certifying agent(s) to which application had previously been made, the year(s) of application, and the outcome of the application(s) submission. We have amended this requirement by adding ''including a copy of any notification of noncompliance or denial of certification issued to the applicant for certification and a description of the actions taken by the applicant to correct the deficiencies noted in the notification of noncompliance, including evidence of such correction.'' We have added this provision to clarify what we mean by ''the outcome of the application(s) submitted.'' This provision is found at § 205.401(c).

(3) *On-site Inspections.* We have combined the arranging for inspection, verification of information, postinspection conference, and additional inspection regulations of the first proposal into a new on-site inspections section, § 205.403. We made this change for the purposes of clarification and the removal of redundancies.

(4) *Additional Inspections.* We have revised the on-site inspections requirements to provide that a State program's governing State official may require a certifying agent to conduct an additional inspection of a production or handling operation to determine the operation's compliance with the Act and these regulations. We have provided State program governing State officials with authority to require additional inspections because such officials will have compliance responsibilities under their State programs and will need such authority to carry out their responsibilities. These requirements are found at § 205.403(a).

(5) *Notifications of Noncompliance.* We have added at § 205.405(b) a provision which identifies for applicants for certification what their options are when they receive a notification of noncompliance. Such applicants may correct the deficiencies and submit a description and supporting documentation of correction to the certifying agent, correct the deficiencies and submit a new application to another certifying agent along with the notification of noncompliance and a description and supporting documentation of correction, or submit written information to the certifying agent to rebut the noncompliance described in the notification of noncompliance.

(6) *Reapplying After a Notice of Noncompliance or Denial of Certification.* We have added a new provision which requires a certifying agent to treat an application for certification as a new application when such application includes a notification of noncompliance or a notice of denial of certification. While the new application may contain the same organic system plan and other information provided in the unsuccessful application for certification, it must also provide any new information or changes in operations which may have occurred since the filing of the unsuccessful application. The updated information concerning the applicant's operation must include a description of actions taken, with supporting documentation, to correct the deficiencies identified in the notification of noncompliance. This new provision is found at § 205.405(e).

Subpart F—Accreditation of Certifying Agents

This subpart sets forth the requirements for a national program to accredit State and private entities as certifying agents to certify domestic or foreign organic production or handling operations. This subpart also provides that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government.

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of United States organically produced agricultural commodities. The accreditation requirements in these regulations will replace the organic assessment voluntary, fee-for-service program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, ''General Requirements for Bodies Operating Product Certification Systems'' (ISO Guide 65).[2] ISO Guide 65 provides the general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 is used as a benchmark in developing the accreditation program described in this proposed rule. Certifying agents accredited under the NOP that maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

Participation in the NOP does not preclude the accredited certifying agent from conducting other business operations, including the certification of agricultural products, practices, and procedures. An accredited certifying agent may not, however, engage in any business operations or activities which would involve the agent in a violation of or a conflict of interest under the NOP.

Proposal Description

The Administrator will accredit qualified domestic and foreign applicants in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify domestic or foreign production or handling operations as certified organic operations. Qualified applicants will be accredited for 5 years.

Application Process. Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations.

[2] ISO/IEC Guide 65 is available for viewing at USDA–AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212–642–4900; Facsimile: 212–398–0023.

Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation.

The administrative information submitted by the applicant should include copies of their procedures for certifying operations, for ensuring compliance of their certified operations with the Act and regulation, for complying with recordkeeping requirements, and for making information available to the public about certified operations. The procedures for certifying operations encompass the processes used by the certifying agent to evaluate applicants, make certification decisions, issue certification certificates, and maintain the confidentiality of any business information submitted by the certified operation. The procedures for ensuring compliance of the certified operations would include the methods used to review and investigate certified operations, for sampling and residue testing, and to report violations.

The personnel information submitted with the application should demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that these employees have revealed existing or potential conflicts of interest.

Applicants who currently certify production or handling operations must also submit a list of the production and handling operations currently certified by them. For each area in which the applicant requests accreditation, the applicant should furnish copies of inspection reports and certification evaluation documents for at least three operations. If the applicant underwent any other accrediting process in the year previous to the application, the applicant should also submit the results of the process.

Certifying agents are prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the certification program. The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation. Certifying agents are prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the certification program.

Statement of Agreement. Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another U.S. Department of Agriculture (USDA)-accredited certifying agent as equivalent to its own and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) Conduct an annual performance appraisal for each inspector used; (2) have an annual program evaluation conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such evaluations; and (3) implement measures to correct any deficiencies in compliance with the Act and regulations identified in an inspector performance appraisal or program evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. A private entity certifying agent must also agree to make such records available to any applicable State program's governing State official.

Approval of Accreditation. Upon receiving all the required information, including the statement of agreement, and the required fee, the Administrator will determine if the applicant meets the requirements for accreditation. The Administrator's determination will be based on a review of the information submitted and, if necessary, a review of the information obtained from a site evaluation. The Administrator will notify the applicant of approval of accreditation in writing. The notice of accreditation will state the area(s) for which accreditation is given, the effective date of the accreditation, and, for a private-entity certifying agent, the amount and type of security that must be established.

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided, in accordance with § 205.665, with a notification of noncompliance and given an opportunity to come into compliance. After receipt of a notification of noncompliance, the applicant may submit a description of the actions taken to correct the noted deficiencies and evidence demonstrating such corrections or file an appeal with the Administrator. If the applicant is successful in its appeal or provides acceptable evidence demonstrating correction of the deficiencies, the Administrator will notify the applicant of accreditation. If the applicant fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, fails to file an appeal by the date specified in the notification of noncompliance, or is unsuccessful in its appeal, the Administrator will issue a written notification of accreditation denial to the applicant. An applicant who has

received written notification of accreditation denial may apply for accreditation again at any time.

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification. The certifying agent also may not require compliance with any production or handling practices other than those provided for in the Act and regulations as a condition for use of its identifying mark. This provision does not apply to States with more restrictive requirements approved by the Administrator or private-entity certifying agents certifying operations within such States.

Site Evaluations. One or more representatives of the Administrator will perform site evaluations for each certifying agent in order to examine the certifying agent's operations and to evaluate compliance with the Act and regulations. Site evaluations will include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. A site evaluation of an accreditation applicant will be conducted before or within a reasonable time after issuance of the applicant's notification of accreditation. Certifying agents will be billed for each site evaluation conducted in association with an initial accreditation, amendments to an accreditation, and renewals of accreditation. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Administrator finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Administrator will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the deficiencies, report the corrections by the date specified in the notification of noncompliance, or file an appeal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may apply for accreditation again at any time. A private-entity certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

Peer Review Panels. The Administrator may establish a peer review panel to assist in evaluating applicants for accreditation. Peer review panels will be used at the discretion of the Administrator following the site evaluation of a certifying agent, but under no circumstances will the Administrator convene a peer review panel when the peer review pool does not contain sufficient persons qualified to peer review the certifying agent.

To be eligible to serve on a peer review panel, the applicant for membership in the peer review pool must provide the Administrator with a written description and, upon request, supporting documentation of its qualifications to conduct peer reviews. The applicant for membership in the peer review pool must address possible limitations on availability to serve and include information concerning commercial interests with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation will be appointed to a panel evaluating such applicant for accreditation or renewal of accreditation. Persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until they are no longer qualified, whichever occurs first. Peer reviewers will serve without compensation.

Peer review panels will consist of at least three but no more than five members. A Department representative will preside over the panel. A peer review panel will include no fewer than two members who possess sufficient expertise in the certifying agent's areas of accreditation. Peer review panels may include up to two members with expertise in other disciplines, including organizational management and finance; member(s) from the approved State organic certification program when the applicant is a private entity that will operate within the State; and member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country.

Each person on a peer review panel must individually review the site evaluation report prepared by the Department's evaluator(s) and any other information that may be provided by the Administrator relevant to continuing or renewing the accreditation status of a certifying agent. Information about the certifying agent received as part of the review process is confidential information, and peer reviewers must not release, copy, quote, or otherwise use material from the information received other than in the report required to be submitted. Each peer reviewer must agree to treat the information received for review as confidential.

A peer review panel meeting will be held solely for the purposes of exchanging information. Any meeting or conference call will be conducted in a manner that will ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually. We do not believe that it is usual to have consensus in peer review or that it is the best use of USDA resources or the time of peer reviewers to seek consensus under a single report. Further, requiring a consensus report may make peer review panels subject to the Federal Advisory Committee Act, which might stifle meaningful dialog between reviewers, increase the cost and time required of peer reviewers for peer review service, and result in problems obtaining volunteers for service on peer review panels.

Peer review panel members will prepare and submit individual reports, including recommendations, to the Administrator regarding a certifying agent's ability to conduct and perform certification activities. The Administrator will consider the reports when determining whether to continue or renew the certifying agent's accreditation. Copies of the peer review panel reports will be provided, upon request, to the certifying agent, and written responses from the certifying agent may be submitted for consideration by the Administrator. Copies of peer review panel reports may be provided to any person requesting such reports under the Freedom of Information Act.

Continuing Accreditation. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of its business information, including its fees, and information evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description of measures implemented in the

previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent inspector performance appraisals and annual program evaluation and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the appraisals and evaluation; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by: (1) Providing the Administrator with a copy of any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance; and (2) on a quarterly calendar basis, the name, address, and telephone number of each operation granted certification.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61 [3] requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

An accredited certifying agent must provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and these regulations. The certifying agent must maintain strict confidentiality with respect to its clients and not disclose to third parties (with the exception of the Secretary or the applicable State program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing these regulations except as authorized by regulation. A certifying agent must make the following information available to the public: (1) Certification certificates issued during the current and 3 preceding calender years; (2) a list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, and the effective date of the certification, during the current and 3 preceding calender years; and (3) the results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calender years. A certifying agent may make other business information available to the public if permitted in writing by the producer or handler. This information will be made available to the public at the public's expense.

An accredited certifying agent must maintain records according to the following schedule: (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and (3) records created or received by the certifying agent pursuant to the accreditation requirements, excluding any records covered by the 10-year requirement must be maintained for not less than 5 years beyond their creation or receipt. Examples of records obtained from applicants for certification and certified operations include organic production system plans, organic handling system plans, application documents, and any documents submitted to the certifying agent by the applicant/certified operation. Examples of records created by the certifying agent regarding applicants for certification and certified operations include certification certificates, notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memoranda concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance appraisals and supporting documents; conflict of interest disclosure reports and supporting documents; annual program evaluation working papers, memoranda, letters, and reports; fee schedules; quarterly reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State program's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable State program's governing State official all records or copies of records concerning its certification activities.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation. Coverage of the conflict of interest provisions extends to immediate family members of the certifying agent; responsibly connected persons of the certifying agent; and any employee, inspector, contractor, or other personnel of the certifying agent. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel

[3] ISO/IEC Guide 61 is available for viewing at USDA–AMS, Transportation and Marketing Programs, Room 2945—South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212–642–4900; Facsimile: 212–398–0023.

of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, any such person must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the certification program.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Renewal of Accreditation. To avoid a lapse in accreditation, certifying agents must apply for renewal of accreditation 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

Following receipt of the certifying agent's annual report and fees, the results of a site evaluation, and, when applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

Accreditation—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Equivalency of Imported Organic Products.* We have removed the regulations on equivalency of imported organic products included in the first proposal. In this proposal, we have added foreign certifying agents as entities eligible for accreditation as certifying agents qualified to certify domestic and foreign organic production and handling operations. We have also added to subpart A definitions for private entity and State entity. We have defined ''private entity'' as any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services. We have defined ''State entity'' as any domestic or foreign governmental subdivision providing certification services.

In commenting on the first proposal, several commenters expressed confusion as to how the Secretary would determine equivalency of imported organic products. They also expressed confusion as to how the Secretary would ensure that imported products met the same requirements as those produced domestically. We have addressed these concerns by adding foreign certifying agents as private or state entities that may be accredited under the NOP. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government. These changes ensure that all certifying agents, including foreign private and state certifying agents, will be required to meet the same requirements to be recognized as qualified to certify organic production or handling operations. This change provides foreign private and state certifying agents with transparent standards for accreditation.

A commenter raised concerns that we acted in violation of international agreements and domestic policy by proposing rules that were contrary to internationally accepted organic standards and, thus, created an unacceptable barrier to trade. The Act directs the Secretary to establish national standards governing the marketing of certain agricultural products as organically produced products. In accordance with our international agreements, this proposal ensures that, with respect to accreditation under this subpart, products imported from the territory of any country are being accorded treatment no less favorable than that accorded to products of U.S. origin. However, in accordance with our international trade agreements and upon implementation of this program, the Administrator will give positive consideration to accepting as equivalent technical regulations of other countries, even if these regulations differ from our own, provided such regulations fulfil the objectives of this proposed program. Any such equivalency agreements will be negotiated on a case-by-case basis, and ample opportunity for public comment will be provided before and during the negotiation process.

Two commenters requested that the Secretary recognize international accreditation systems for foreign organic certification programs and establish the requirements for approval of such systems in this proposal. We have instead proposed for the purposes of this rule that all certifying agents, regardless of their country of origin, meet the same requirements for accreditation through the provisions of this subpart.

One commenter requested that all imported organic products be labeled by their respective country of origin. The purpose of this proposal is to provide the requirements for the marketing of agricultural products in the United States that are labeled or sold as organic. The issue of country-of-origin labeling of imported products is not related to this proposal or the Act. Further, regulations pertaining to the labeling of organic agricultural products should not be used to enforce country-of-origin labeling requirements.

Several commenters stated that the first proposal did not take into account

the use of equivalency to ensure the marketing of U.S. organic products in foreign markets. The Department will work to oppose other countries' organic regulations that would prohibit entry of U.S. organic product produced under the Act or these regulations. As appropriate, the U.S. Government may represent U.S. organic interests in international government-to-government bodies. However, neither of these objectives is intended to be achieved by this rule.

(2) *Accreditation Requirements Regarding Expertise of Employees.* We have added a new regulation to the general requirements for accreditation. This regulation requires that the certifying agent ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to sufficiently perform the duties assigned. Certifying agents were required under the first proposal to use a sufficient number of adequately trained personnel, including inspectors. They were also required to conduct an annual performance appraisal of each inspector.

Commenters felt that the proposed rule did not sufficiently ensure that certifying agents would employ qualified individuals. One of these commenters requested that we require organic certification inspectors to participate in an inspector accreditation program, such as that offered by the Independent Organic Inspectors Association. We believe that inspector participation in an inspector accreditation program should be left to the discretion of the inspector and certifying agent. However, we believe that the new requirement combined with the requirements from the first proposal should ensure that responsibly connected persons, employees, and contractors of an accredited certifying agent are qualified to perform their inspection, analysis, and decision-making duties. This new regulation is found at § 205.501(a)(5) of this proposal.

(3) *Recordkeeping Requirements.* We have proposed a new § 205.510(b), which identifies three categories of records and their retention periods. This new paragraph was added to address commenter concern that the requirement that an accredited certifying agent maintain records about all of its activities for 10 years was excessive and unnecessary. Commenters suggested a 5- to-7-year retention period. We agree that for some records, a retention period of 10 years may be excessive. Accordingly, in this proposal, we are proposing three retention periods. First, records created by the certifying agent regarding applicants for certification and certified operations would have to be maintained for not less than 10 years beyond their creation. We believe this retention period to be consistent with the Act's requirement that the certifying agent maintain all records concerning its activities for a period of not less than 10 years. Second, records obtained from applicants for certification and certified operations would have to be maintained for not less than 5 years beyond their receipt. This retention period is the same as that required by the Act for the retention of records by the certified operation. Since the certified operation can dispose of its records 5 years after their creation, the certifying agent should also be able to dispose of those records it receives from the certified operation 5 years after their receipt. Third, records created or received by the certifying agent for USDA accreditation would have to be maintained for not less than 5 years beyond their creation or receipt.

(4) *Conflict of Interest Provisions.* We have made three changes which we believe will strengthen the conflict of interest provisions. We have made these changes because we concur with the comment from a research foundation stating that the provisions for preventing conflicts of interest needed to be significantly strengthened. First, we have added a new § 205.501(a)(11)(v), which requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification of an operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certifying agent. Second, coverage of the conflict of interest provisions has been extended to immediate family members of the certifying agent; responsibly connected persons of the certifying agent; and any employee, inspector, contractor (to be used in the certification of an operation), or other personnel of the certifying agent. Immediate family members would include the spouse; minor children, including legally adopted children; or blood relatives who reside in the immediate household of a certifying agent; responsibly connected person of the certifying agent; or any employee, inspector, contractor, or other personnel of the certifying agent. Third, this proposal lists contractors among those persons who are prohibited from accepting payment, gifts, or favors of any kind, other than regular fees from any business inspected by the certifying agent. This addition, which is found at § 205.501(a)(11), was made to clarify that contractors, including contract inspectors, are prohibited from accepting payment, gifts, or favors of any kind, other than regular fees.

(5) *Use of Voluntary Labor.* We have added an exception to the prohibition of the acceptance of payment, gifts, or favors of any kind. The exception provides that any certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government may accept voluntary labor from certified operations. Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition from its government is required as verification of the certifying agent's status as a not-for-profit organization. This change was made to clarify our original intent that not-for-profit certifying agents would be allowed to accept volunteer labor from persons certified by the certifying agent.

In the preamble to the first proposal, we stated that we would not consider a volunteer who performs services for a not-for-profit certifying agent as providing favors to any particular individual in that agency and, therefore, would not consider the certifying agent as being in a conflict of interest situation by accepting such services from volunteers. We have made this clarification because a commenter expressed the belief that the certifying agent should be allowed to receive donations of time, food, and money beyond any mandatory fees from persons they certify. The Act prohibits certifying agents from accepting payments, gifts, or favors of any kind from a business inspected, other than prescribed fees. Accordingly, this exception is limited to acceptance of voluntary labor by not-for-profit certifying agents. While § 205.501(a)(11)(iii) prohibits the acceptance of payments, gifts, or favors of any kind, other than prescribed fees, from any business inspected for certification as a producer or handler of organic agricultural products, the paragraph does not prohibit the accredited certifying agent from accepting payments, gifts, or favors of any kind, including time, food, or money, from persons for whom they do not provide inspections for certification as a producer or handler of organic agricultural products.

(6) *Certification Fees.* We have removed the requirement that a certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. We have made this change because we concur with those commenters who expressed the belief that certifying agents should be permitted to set their own fees without the approval of the Secretary. However, we continue to believe that the Administrator should retain oversight of the fees, not for the purpose of setting the fees or of dictating the level of the fees, but for the purpose of determining if any certifying agent's fees are so high as to be unreasonable and to ensure that the schedule of fees filed with the Administrator are applied uniformly and in a nondiscriminatory manner. The Administrator should also retain the ability to inform a certifying agent that its fees appear to be unreasonable and to require a justification for the level of fees set by the certifying agent. We further believe that the Administrator should retain the ability to investigate the level of fees charged by an accredited certifying agent if a complaint is made or if compelling circumstances warrant such an investigation. Accordingly, we have proposed at § 205.501(a)(15) that a certifying agent must charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. We have also included at § 205.642 regulations with respect to fees charged by certifying agents to producers and handlers. Section 205.642 is discussed under fees in subpart G of this preamble.

(7) *State Standards That Vary From the National Organic Program.* We have added an exception to the regulation which prohibited certifying agents from requiring, as a condition for use of the certifying agent's identifying mark, compliance with any farming or handling requirements other than those provided for in the Act and regulations. The exception provides that the requirement does not apply to States with more restrictive requirements approved by the Secretary or private entity certifying agents certifying production or handling operations within States with more restrictive requirements approved by the Secretary. This change was made because we agree with the State commenters who stated that the prohibition on requiring compliance with any farming or handling requirements other than those provided for in the Act and regulations would prohibit States from requiring that their more restrictive standards, approved by the USDA, be met as a requirement for use of the State's logo on organically produced products. We did not intend to prohibit States from requiring that their more restrictive standards be met as a requirement for use of the State's logo on organically produced products. Including this exception in § 205.501(b)(2) will permit States with more restrictive requirements approved by the Secretary and private entity certifying agents certifying production or handling operations within the borders of such States to require that the State's more restrictive standards be met as a requirement for use of their logo or other identifying mark on organically produced products.

Certifying agents may not require a certified operation to meet production or handling standards greater than those established by the Department or, when applicable, an approved State organic certification program as a condition for using its logo or other identifying mark. However, a certifying agent may verify, upon the request of a producer or handler certified by the certifying agent, that the producer or handler is meeting contractual specifications which include requirements in addition to those of the Act and regulations.

(8) *Time Period for Public Access to Information.* For the requirement that certifying agents describe the procedures they will use for making information available to the public, we have changed the time period from ''during the 10-year period preceding the receipt of the request from the public'' to ''during the current and 3 preceding calendar years.'' Commenters stated that the required 10-year period was excessive and unnecessary. The Act requires public access to certification documents and laboratory analyses that pertain to certification. However, the Act does not specify that a certifying agent must provide access to its records throughout their 10-year retention period. We agree with the commenters that public access to the records the certifying agent is required to keep should be limited to a reasonable period short of the full retention period. Such a reasonable period, we believe, would be the current calendar year and the 3 calendar years preceding the calendar year of the request. Accordingly, § 205.504(b)(5) requires certifying agents to describe the procedures they will use for making information available to the public during the current and 3 preceding calendar years. This time period will lessen the burden on certifying agents while assuring reasonable public access to such records.

(9) *Scope of Information for Public Release.* We have expanded the scope of information for public release which must be included in the list of producers and handlers whose operations the certifying agent has certified. Specifically, certifying agents will have to include the name of the operation and type(s) of operation in its list of producers and handlers it has certified. This change is included in section § 205.504(b)(5)(ii). Commenters requested that the list be expanded to include the name of the operation, its physical location(s), certification history, type(s) of operation, acreage (when applicable), and person responsible for organic regulation compliance. While we agree that the name of the operation and type(s) of operation should be available to the public, we believe that the certified operation's physical location(s), certification history, and acreage are confidential information which has no relationship to the operation's status as a certified organic operation. Therefore, such information should only be made available with the written consent of the certified operation. We also believe that it is unnecessary to list a person responsible for organic regulation compliance since the applicant ultimately has that responsibility. Therefore, these requested additions have not been made. We have also removed the separate requirement that certifying agents identify for the public the organic agricultural products produced by each certified operation. We have taken this action because the information is available on the certificates and the list of producers and handlers required to be released by the certifying agent to the public. These requirements are found at § 205.504(b)(5)(i) and (ii).

(10) *Release of Nonconfidential Business Information.* We have removed the requirement that certifying agents provide a description of the procedures to be used to make nonconfidential business information, as permitted by the producer or handler and approved by the Secretary, available to the public. This requirement has been replaced with the requirement that the certifying agent provide a description of the procedures to be used to make other business information, as permitted in writing by the producer or handler, available to the public. Commenters objected to the requirement that the Secretary approve the release of nonconfidential business information that the producer or handler had authorized the certifying agent to

release. They believed that this requirement lacked justification and created unnecessary costs. We concur that this requirement is unnecessary. However, we believe that the producer's or handler's approval must be obtained in writing, which is reflected in this proposal at § 205.504(b)(5)(v).

(11) *Submission of Applicant's Financial Policies and Procedures.* We have removed the requirement that a certifying agent include with its application for accreditation a description of its policies and procedures for collection and disbursement of funds and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers. Commenters stated that they did not believe the submission of applicant financial policies and procedures was necessary. We have decided that the information requested probably would not fully meet our needs in determining that certification decisions were not influenced by the certifying agent's concern for the certification decision's financial impact on the certifying agent or in determining compliance with the conflict of interest provisions of the Act and these regulations. Accordingly, this requirement is not included in this proposal.

(12) *Submission of Information Concerning Current Certification Activities.* We have changed the voluntary submission of information and documents concerning current certification activities to a required submission. Commenters stated that the submission of a list of all farms, wild-crop harvesting operations, and handling operations currently certified by the applicant should be required. They went on to say that the submission of copies of the inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year should remain optional. They also said the submission of results from any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities should remain optional.

We agree with the commenters that a list of all operations currently certified by the applicant should be a required submission. We also believe that copies of inspection reports, certification evaluation documents, and accreditation results should be a required submission from all applicants currently certifying production or handling operations. Accordingly, at § 205.504(d) we have made the submission of information and documents concerning current certification activities mandatory for certifying agents currently certifying production or handling operations.

This change has been made because of the value such information and documents would have in assisting the Department in evaluating an applicant for accreditation. However, we have limited the submission of inspection reports and certification evaluation documents for production and handling operations certified by the applicant. The applicant is required to submit copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested. We have limited the submission to reduce the reporting burden on certifying agents. The Administrator may, however, require that the certifying agent submit additional inspection reports and certification evaluation documents.

We recognize that a newly organized certifying agent with no experience would be unable to supply the information. An applicant's inability to provide the information and documentation required by the revised paragraph due to lack of experience would not be prejudicial to the Department's evaluation of the application.

(13) *Site Evaluations.* We have revised the site evaluation provisions to clarify the scope of an evaluation, to specify that the evaluation will be arranged and conducted by a representative of the Administrator, and to specify when evaluations shall or may be conducted. These changes are made in response to commenters who suggested adding details to the regulatory text regarding the nature of site evaluations. The revised section provides that site evaluations of accredited certifying agents shall: (1) Be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and regulations; (2) include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent; (3) be conducted by a representative(s) of the Administrator; and (4) be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. This revised section provides that an initial site evaluation of an accreditation applicant would be conducted before or within a reasonable period of time after issuance of the applicant's notification of accreditation. Section 205.508 also provides that one or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements for accreditation.

(14) *Eligibility for Peer Review Panels.* We have added a new regulation addressing eligibility for peer review panels. Commenters expressed concern that peer review pool applicants be free of conflicts of interest and possess the necessary expertise in organic production or handling. The first proposal provided that candidates for membership in the peer review panel pool would be required to submit a letter to the Program Manager of the NOP requesting appointment, describing their qualifications, and identifying conflicts of interest. We believe that there is value to the applicants for membership in the peer review panel pool and the general public in addressing eligibility for peer review panels in the regulatory text. Accordingly, we have added a new regulation at § 205.509(b) which provides that applicants for membership in the peer review panel pool must provide the Administrator with a written description and, upon request, supporting documentation of their qualifications to conduct peer reviews. Such description must include information concerning the applicant's training and expertise in organic production or handling methods and in evaluating whether production or handling operations are using a system of organic production or handling. Applicants must also address their possible limitations on availability to serve. Further, applicants would be required to include information concerning their commercial interests and those of their immediate family members, within the 12-month period prior to application, with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation will be appointed to or accept appointment to a panel evaluating the applicant. This provision was added for the purpose of avoiding conflicts of interest by peer reviewers. This new regulation also provides that persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until

they are no longer qualified, whichever occurs first.

(15) *Composition of Peer Review Panels.* We have revised the regulations concerning the composition of peer review panels. Commenters requested that the peer review panel consist of at least two members who are not USDA employees, rather than not AMS employees. We agree with this suggested change, which clarifies what had been our intent. This change is included in § 205.509(c). Section 205.509(c) provides that peer review panels shall consist of at least three but no more than five members. This section provides that peer review panels must include a Department representative who will preside over the panel and no fewer than two members from the peer review pool who possess sufficient expertise in the relevant areas of accreditation. Additionally, section 205.509(c) provides that peer review panels may include up to two members with expertise in other disciplines, including organizational management and finance; member(s) from the approved State organic certification program when the applicant is a private entity seeking accreditation within the State; and member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country. We have added authorization for these additional members to broaden the scope and depth of expertise available to peer review panels.

Commenters also expressed concern that the peer review panels consist of at least one member from a State organic certification program. We do not believe that the composition of peer review panels regulations needs to be amended to accommodate this concern. To the extent possible, accredited private certifying agents will peer review private certifying agents, and accredited State certifying agents will peer review State certifying agents.

(16) *Renewal of Accreditation.* We have revised the renewal of accreditation provisions to, among other things, require that an accredited certifying agent's application for accreditation renewal be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The first proposal provided that an accredited certifying agent would request renewal of accreditation on or before the fifth anniversary of issuance of the notice of confirmation of accreditation and each subsequent renewal of accreditation. Commenters expressed concern about whether the accredited certifying agent's accreditation would lapse during the renewal process. They suggested that certifying agents should submit their application for renewal of accreditation 6 months prior to the fifth anniversary of issuance of the notice of confirmation.

We believe that clarification regarding the status of the certifying agent's accreditation during the renewal process is appropriate. We also concur with the commenters' suggestion that certifying agents should submit their applications for renewal of accreditation 6 months prior to the fifth anniversary of issuance of the notice of confirmation. We have replaced ''notice of confirmation of accreditation,'' however, with ''notification of accreditation'' because this proposal eliminates the section on confirmation of accreditation. Accordingly, we have provided in this proposal at § 205.510(c) that: (1) An accredited certifying agent's application for accreditation renewal must be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation; (2) the accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process; (3) the accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date; (4) certifying agents with an expired accreditation must not perform certification activities under the Act and regulations; and (5) following receipt of the information submitted by the certifying agent, the results of any site evaluation, and, when applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed.

These changes would provide the Department with sufficient time to fully process the certifying agent's application for accreditation renewal prior to the accreditation's scheduled date of expiration. This revised regulation also clarifies that a certifying agent's accreditation will not expire during the accreditation renewal process if the certifying agent has made timely application for renewal. It also makes clear that the accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. This regulation also provides that certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

(17) *Denial of Accreditation.* We have revised the denial of accreditation regulations to clarify that after receipt of a notification of noncompliance, the applicant may submit a description of the actions taken to correct the noted deficiencies and evidence demonstrating such corrections, rather than submitting a new application. We have taken this action because commenters were confused by our reference to a new application in the denial of accreditation regulations. The denial of accreditation regulations are found at § 205.507 in this proposal.

Accreditation—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Durations of Accreditation and Reporting Requirements.* Commenters expressed concern regarding the duration of accreditation and whether the interval of required reporting is adequate. An association expressed concern regarding the economic impact of accreditation on small certifying agents. This commenter stated that small certifying agents should not be accredited more often than every 5 years. An international organic federation expressed the belief that accreditation for 5 years is too long. The commenter went on to say that certification bodies are expanding rapidly and that annual reports cannot be relied upon to fully convey the consequent changes. This commenter believes that many of the conditions of accreditation may relate to operational aspects that cannot be addressed in an annual report.

Annual reporting by the certifying agent, under this proposal, would provide: (1) A complete and accurate update of applicant information and expertise and ability information previously submitted; (2) information supporting any changes being requested in the areas of accreditation; (3) the measures that were implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary as specified in the most recent notification of accreditation; and (4) the results of the most recent inspector performance appraisal and program evaluation and adjustments to the certifying agent's operation and procedures implemented and intended to be implemented in response to the appraisals and evaluations. This proposal includes a requirement at

§ 205.501(a)(14) that the certifying agent submit to the Administrator a copy of each notification of: (1) Denial of certification; (2) noncompliance; (3) noncompliance correction; (4) proposed suspension or revocation; and (5) suspension or revocation, simultaneously with its issuance.

We believe that these reporting requirements, coupled with feedback from applicants for certification, certified operations, and other interested parties, will provide the Department with sufficient information regarding the certifying agent and its operation to determine whether a site visit is necessary to evaluate the certifying agent's suitability to remain accredited. Under this proposal, the Department will conduct one or more site evaluations during the period of accreditation to determine whether the accredited certifying agent is complying with the requirements for accreditation. Accordingly, we believe the duration of accreditation period first proposed was correct, and we are, therefore, reproposing this time period at § 205.500(b).

(2) *Performance Appraisals and Program Evaluation.* Comments from State departments of agriculture and some certifiers indicated that the annual inspector performance appraisal and annual program evaluation requirements duplicated State requirements. The commenters asked what the required scope and depth of evaluations was expected to be, whether third party evaluators would be required to be used to assess the performance of the operation, and whether existing performance appraisal and program evaluation practices of a certifying agent would be used to meet the annual inspector performance appraisal and program evaluation requirements.

We do not intend for States to develop dual performance appraisal and program evaluation programs. We believe that performance appraisals and program evaluations conducted to meet State requirements will also meet the requirements of this proposal. State and private agency personnel performance appraisals and program evaluations would be expected to be consistent with good management practices and appropriate to the organization's size and structure. This could be different for different organizations. Therefore, we are not prescribing the specific performance appraisal system or instrument to be used to assess inspector performance, the specific program evaluation methods that must be used, or that third parties must conduct the required program evaluation. Accordingly, we have not changed the questioned provisions, which appear at § §205.501(a)(6) and (7). We have, however, revised § 205.501(a)(7) to clarify that the annual program evaluation can be conducted by the certifying agency staff, an auditing entity, or a consultant who has expertise to conduct program evaluations.

(3) *''Open Records'' Requirements.* Commenters expressed the belief that confidentiality requirements for certifying agents might conflict with State requirements for ''open records.'' We recognize this potential for conflicting requirements. Records collected and maintained under the NOP are subject to the confidentiality provisions of the Act and these regulations. However, a State-entity certifying agent will be subject to its State ''open records'' laws when such laws conflict with the confidentiality provisions of the Act and these regulations. Records collected and maintained under the NOP by a private entity certifying agent will always be subject to the confidentiality requirements of the Act and these regulations. Accordingly, pursuant to the Act, we are reproposing the confidentiality provisions at § 205.501(a)(10).

To clarify that authorized representatives of the Secretary or the applicable State program's governing State official may act on behalf of the Secretary or the State program's governing State official and must be given access to the records, we have added the phrase, ''or their authorized representatives,'' to § 205.501(a)(10). Such representative could be a member of the NOP staff, a Department compliance officer, or other official. This provision is standard practice and is necessary for Government oversight of a regulatory program.

(4) *List of Confidential Records.* One commenter requested a definitive list of the records that had to be kept confidential. We cannot create such a list because it is not possible to describe every record that would be characterized as a business-related record. Such records would include, however, organic production and handling plans, records that are related to trade secrets and commercial or financial information obtained from applicants for certification, and records or information compiled for an investigation into alleged noncompliance with the Act and regulations.

(5) *Time Period for Prohibition of Commercial Interest.* We received many comments regarding the prohibition of commercial interest in an organic production or handling operation during the 12 months prior to certification. Several States and industry associations stated that the prohibition of commercial interest should apply to the 12 months after as well as the 12 months prior to certification. These commenters offered no reasoning for their position. A research foundation recommended that the prohibition of commercial interest should be for 3 years before and after the application for certification. This commenter stated that the conflict of interest provisions needed significant strengthening. A producer commenter stated that the prohibition of commercial interest should be for an indefinite period, not for 12 months. Some commenters recommended that certifying agents and responsible parties and employees of certifying agents be barred from accepting employment for 1 to 3 years from any certified production or handling operation in which they participated in any manner in the operation's certification. An accreditation service stated it believed there would be a conflict of interest should a consulting or business connection arise between an inspector and a production or handling operation following the site evaluation. This commenter presented the example of an inspector being offered employment during the site evaluation but not taking the position until 6 months after the site evaluation. Many commenters, however, supported our proposed prohibition of commercial interest in an organic operation during the 12 months prior to certification.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period and with the recommendations for a postcertification prohibition period for those persons no longer associated with the certifying agent. Regarding the recommendations for a longer precertification prohibition period, we continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, we have added a new section, 205.501(a)(11)(v), which requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties

responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have decided to repropose the prohibition on commercial interest in an applicant for certification for a 12-month period prior to the application for certification at section § 205.501(a)(11).

Regarding the recommendations for a postcertification prohibition period for those persons no longer associated with the certifying agent, we believe such a period is unnecessary. We take this position because certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this proposal.

(6) *Conflicts of Interest.* Some commenters stated that they understood the proposed conflict of interest provisions to prohibit certifying agents from certifying any organic operation owned or operated by a member of the certifying agent's board of directors or from certifying any organic operation owned or operated by an employee of the certifying agent. One commenter stated that because certification arose from the ranks of organic farmers, there are many certification personnel, including inspectors, who also farm or have family who farm. This commenter stated that it should be permissible for a certifying agent to review and certify an organic operation owned or operated by a responsibly connected person or employee, provided that the responsibly connected person or employee is excluded from the decision-making process with respect to the organic operation to be certified.

The commenters are correct in their interpretation that the first proposal prohibited certifying agents from certifying an operation when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the operation. This prohibition is limited, however, to the 12-month period prior to the application for certification. The first proposal did not prohibit certifying agents from certifying an operation when an employee of the certifying agent has or has held a commercial interest in the operation. The first proposal prohibited a certifying agent from using an employee in any phase of the certification process when such employee has or has held a commercial interest in an operation making application for certification within the 12-month period prior to the application for certification. A responsibly connected party is any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant for or a recipient of certification or accreditation.

We believe that a certifying agent and a responsibly connected party of such certifying agent hold positions of power and authority which preclude the certification of an operation in which they have or have held a commercial interest during the 12-month period prior to an application for certification. The certifying agent's control over the employment of an agent's employee makes it unreasonable to expect an employee of a certifying agent to impartially carry out the employee's duties when the certifying agent or a responsibly connected party of such agent has an interest in the applicant. Such is not true of an employee who is subordinate to the certifying agent or a responsibly connected party of the certifying agent. Accordingly, we have reproposed the requirement that a certifying agent prevent conflicts of interest by: (1) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest within the 12-month period prior to the application for certification and (2) excluding any person with a conflict of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which the person has or has held a commercial interest within the 12-month period prior to the application for certification. Both of these provisions are found in § 205.501(a)(11).

(7) *Defining Commercial Interest.* A research foundation recommended that the provisions for preventing conflicts, found in this proposal at § 205.501(a)(11), be strengthened by changing ''a commercial interest in the operation'' to ''a commercial interest in the operation or the marketing or distribution of its products.'' We believe that the recommended addition is unnecessary because ''commercial interest'' covers all business transactions between the certifying agent or responsibly connected parties, employees, inspectors, contractors, or other personnel of the certifying agent and the applicant for certification or certified operation. This interpretation would not apply to voluntary labor provided, in accordance with § 205.501(a)(11)(iii), by a certified operation to a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption. Further, this interpretation would not apply to the providing of advice, in accordance with § 205.501(a)(11)(iv), concerning organic practices or techniques to any certification applicant or certified operation when such advice is covered by fees under the applicable certification program established under the Act.

(8) *Provision of Information to Producers and Conflicts of Interest.* Commenters were concerned about the effect that some of the conflict of interest provisions would have on certifying agents that provide producers with information on organic practices through forums such as in-house publications, conferences, workshops, informational meetings, and field days

for a fee. Specifically, they were concerned about the impact of the conflict of interest provision requiring that certifying agents prevent conflicts of interest by not providing advice concerning organic practices or techniques to any certification applicant or certified organic production or handling operation for a fee, other than as part of the fees established under the applicable certification program established under the Act. These commenters requested that the paragraph be rewritten to clarify that such activities would not be prohibited. We also received a comment stating that advice relating to improving production yields, market access, etc., is not the function of an inspector and can lead to a nonmonetary conflict of interest. This commenter stated that advice, where given, should be restricted to issues related to the understanding and implementation of the standards.

Certifying agents have historically provided advice concerning organic practices or techniques to any certification applicant or certified organic production or handling operation for a fee through forums such as in-house publications, conferences, workshops, informational meetings, and field days. Such activities and their fees would not be prohibited under the Act or these regulations, provided that such activities were not required as a condition for production or handling certification. Section 205.503(c) would require that the applicant for accreditation provide a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant. We would consider such activities to be voluntary participation activities provided by the certifying agent to producers, handlers, and other interested persons under the NOP. We also believe that it is appropriate, as well as industry practice, during an on-site inspection for inspectors to provide advice on a wide range of issues related to an on-site inspection of a production or handling operation. Accordingly, the conflict of interest provisions found at § 205.501(a)(11) have not been rewritten as requested by the commenters.

(9) *Equivalency of Certification Decisions.* We received a variety of comments suggesting changes to the requirement that accredited certifying agents accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own. Several of these commenters asked whether States with more restrictive standards could challenge certification decisions made by any accredited certifying agents. A few commenters representing State programs stated that States should be able to maintain control over which certifying agents operate within their State. Other commenters suggested that the requirement be amended to: (1) Require that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own only after the certifying agent's accreditation has been confirmed by the Department; (2) provide that if a certifying agent doubts the accuracy of another certifying agent's determination, the certifying agent questioning the accuracy can file a complaint with the Secretary; and (3) authorize an accredited certifying agent to request additional documentation from another certifying agent if questions arise regarding the other certifying agent's certification activities or the activities or product of a production or handling operation certified by the other certifying agent.

No organic product may be produced or handled to organic standards lower than the standards of the NOP. To certify organic production or handling operations to the national standards or to more restrictive State standards approved by the Secretary, the certifying agent must be accredited by the Administrator. While States may set more restrictive standards than the national organic standards for product produced or handled within their State, those requirements do not apply to organic product produced or handled outside of such State. Further, a State government may not prevent the marketing or sale in the State of organic product produced in another State to this program's national organic standards. State organic certification programs approved by the Secretary would be required to treat all accredited certifying agents equally. Likewise under this program, accredited certifying agents in one State cannot refuse to recognize another State's product which is certified to these national organic standards.

We disagree with the suggestion to allow certifying agents to challenge the decisions of certifying agents that have not yet had their accreditation confirmed by the Department. We believe that allowing a certifying agent to challenge the certification decisions made by a certifying agent that has not had its site evaluation would create an insurmountable barrier for persons wanting to become accredited under the NOP, especially persons establishing new operations. The proposed accreditation procedures are sufficiently rigorous to permit a well-founded assessment of the applicant's capabilities and qualifications and will allow all eligible certifying agents to receive timely accreditation. We will only accredit certifying agents that we believe possess the expertise and ability to implement the proposed certification program. This includes newly established certifying agents who might require a longer period of time between accreditation and a site evaluation to allow the certifying agent to perform sufficient certification activities for the Department to perform a meaningful site evaluation.

Should questions arise regarding a certifying agent's certification activities, a certified production or handling operation's activities, or the organic status of a certified production or handling operation's product, the questioning certifying agent could report a complaint or allegation of noncompliance, with the certification provisions of this part, to the State program's governing State official or the Administrator. As appropriate, the State program's governing State official or the Administrator will investigate such complaints or allegations. Certifying agents are not authorized to investigate allegations or suspicions of noncompliance by other certifying agents, nor are certifying agents allowed to take unilateral action against an accredited certifying agent, such as refusal to recognize the certification decisions made by another certifying agent.

For the above reasons, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own. This requirement is located at § 205.501(a)(12).

(10) *False or Misleading Claims.* Commenters objected to the requirements that an accredited certifying agent must refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced. A few of these commenters stated that the requirements exceed the authority given by the Act by introducing claims other than those concerning representations of nonorganic product as organic. Additionally, a few commenters believed that the term, ''misleading,'' is too broad and could be interpreted to mean that the certifying agent could make no negative claims about the USDA accreditation program. They suggested that the requirements be amended by removing the reference to misleading claims. Another commenter

believed that the phrase, ''or the nature or qualities of products labeled as organically produced,'' should be deleted because it is vague and would unduly limit the freedom of certifying agents to share information with consumers, farmers, processors, and other interested parties regarding the attributes of organic food and organic production systems, including nutritional properties, freshness, taste, and less reliance on synthetic substances.

We disagree with the commenters who stated that the requirements exceed the authority given by the Act by introducing claims other than those concerning representations of nonorganic product as organic. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the changes suggested by the commenters would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, the requirements are reproposed in this proposal without change at § 205.501(a)(13).

(11) *Notification of Status of Certified Operations.* Comments received on the requirements addressing documentation to be submitted by certifying agents to the Department regarding the status of certified operations suggested that: (1) The public should have access to the notification of certification status documentation; (2) annual reporting by certifying agents of the name of each operation whose application for certification has been approved is sufficient; and (3) the required reporting should only include the name of those operations certified during the quarter being reported rather than a listing of all operations certified by the certifying agent. First, we believe that the Freedom of Information Act adequately provides for public access to information. Second, we need the required information to facilitate oversight and to ensure that we have relatively current data for responding to inquiries involving the granting of certifications by certifying agents. It was not our intent to have certifying agents update their list of certified entities quarterly. Our intent was to receive on a quarterly basis a listing of all certifications granted by the certifying agent during the quarter being reported. Accordingly, no changes have been made on the basis of these comments to the requirements found in this proposal at § 205.501(a)(14).

(12) *Certifier Compliance With Terms and Conditions Deemed Necessary.* Commenters objected to the requirement that certifying agents must comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with § 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, this requirement, found at § 205.501(a)(17), is unchanged in this proposal except to change ''Secretary'' to ''Administrator'' since the Administrator will be responsible for administration of the NOP.

(13) *Limitations on the Use of Certifying Agent's Marks.* Private certifying agents disagreed with the provision that prohibited certifying agents from requiring, as a condition of use of the certifying agent's identifying mark, compliance with any production or handling requirements other than those provided for in the Act and regulations. Private certifying agents commented that they should be allowed to use their identifying mark to recognize additional achievements by producers and handlers that exceed the requirements proposed in the national organic standards. The commenters' position is the same as that suggested by public input prior to publication of the first proposal.

We believe that the private certifying agents' position advocating the use of their identifying mark to recognize additional achievements is inconsistent with § 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. Accordingly, we are reproposing the provision prohibiting certifying agents from requiring, as a condition of use of the certifying agent's identifying mark, compliance with any production or handling requirements other than those provided for in the Act and regulations or under an approved State organic certification program. This reproposed provision is found at § 205.501(b).

(14) *Additional Requirements for Private Certifying Agents.* Commenters expressed concern regarding the three additional requirements for a certifying agent who is a private person. First, private certifying agents expressed concern regarding the requirement that private certifying agents hold the Secretary harmless for any failure on their part to carry out the provisions of the Act and regulations. Their concern focused on the fact that applicants for certification can appeal a certifying agent's refusal to certify to the Secretary and that a certifying agent's recommendation to suspend or revoke a certification can be appealed to the Secretary. They believe that, without the authority to independently deny, suspend, or revoke certification, the certifying agent becomes liable for the actions of the Secretary.

We disagree with the assertion that the certifying agent becomes liable for the actions of the Secretary. The provision clearly states that private certifying agents hold the Secretary harmless for any failure on their part. This in no way would make the certifying agent responsible for any failure on the part of the Department. Further, the wording of this provision is consistent with § 6515(e)(1) of the Act, which provides that private certifying agents shall agree to hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act. Accordingly, we are reproposing this regulation at § 205.501(c)(1).

Second, commenters expressed concern regarding the requirement that certifying agents furnish reasonable security, in an amount and according to terms as the Secretary may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent. The commenters expressed concern regarding what would be the dollar amount of the security, how the dollar amount of the security would be determined, and in what form the security might be furnished. Several commenters expressed concern over the availability of errors and omissions insurance. The commenters also expressed a belief that guidance on what reasonable security might entail will be needed by accreditation applicants to evaluate their costs for accreditation.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's

contractual obligations. As noted elsewhere in this proposed rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by the Department. Such rulemaking will provide for public input and will occur prior to the call for applications for accreditation. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act. Accordingly, we are reproposing this regulation at § 205.501(c)(2).

Third, commenters expressed concern regarding the requirement that a private person accredited as a certifying agent must transfer to the Secretary and make available to any applicable State program's governing State official all records or copies of records concerning the private certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation. This requirement is consistent with § 6515(c)(3) of the Act, which provides that if any private person that was certified under the Act is dissolved or loses its accreditation, all records or copies of records concerning such person's activities under the Act shall be transferred to the Secretary and made available to the applicable State program's governing State official. In addition to being consistent with the Act, we believe that this regulation is necessary to ensure the continuity and integrity of the NOP. Accordingly, we are reproposing this regulation at § 205.501(c)(3).

(15) *Public Access to Applicant Information.* The first proposal included provisions regarding what information had to be submitted by an accreditation applicant. Commenters requested the addition of a paragraph addressing public access to this information about the applicant's organization and intended certification activities. We have not made this requested change because the proposed recordkeeping and availability requirements under this program, coupled with the Freedom of Information Act, adequately provide for public access to information. The regulations on applicant information are found at § 205.503 and include two additions to the provisions of the first proposal. This proposal requires the applicant to provide the name of the person responsible for the certifying agency's day-to-day operations and to submit a copy of its schedule of fees for all services to be provided under these regulations.

(16) *Application Requirements for States.* Commenters stated that State certifying agents should not be required to submit documents and information regarding personnel, administrative policies and procedures, and financial policies and procedures to demonstrate evidence of expertise and ability. They believe that the requirements should not apply to States that have established hiring procedures, standard qualifications for job descriptions, and statewide policies for training, evaluating, and supervising personnel. They also stated that administrative policy and procedure review should be limited to organic program administration, not to agencywide policies or procedures such as financial policies.

We acknowledge that States have established hiring procedures, standard qualifications for job descriptions, administrative procedures, and statewide policies for training, evaluating, and supervising personnel and that such policies and procedures would be applicable to State certifying agents. This fact, however, does not make States uniquely different from private accreditation applicants who would have similar policies and procedures in exercising good business practices. State certifying agents cannot be exempt from these requirements simply because they are a government agency.

We anticipate that a State will submit its established policies and procedures to meet the requirements for demonstrating its expertise in organic production and handling techniques and its ability to fully comply with and implement the national organic certification program. A stated purpose of the Act is the establishment of national standards. We believe such national standards extend to uniform requirements for State and private certifying agents unless otherwise provided by the Act. We further believe the required information is essential to enable the Administrator to make a determination concerning approval of an application for accreditation. Accordingly, the requirements for demonstrating expertise in organic production and handling techniques and an ability to fully comply with and implement the national organic certification program remain the same for private and State certifying agents. These requirements are found at § 205.504.

(17) *Public Access to Information on Certified Operations.* Commenters requested that the public be provided information about a certified operation's farming practices, use of pesticides, and livestock production practices. All production and handling operations must meet the requirements of the national organic certification program to be certified. An accredited certifying agent will determine whether an operation meets those requirements. Certified operations can be held to no other standards except, if applicable, the requirements of an approved State organic certification program. Accordingly, we believe access to the requested information is unnecessary. We also believe the information to be confidential business information that should not be released to the public. Therefore, we have made no changes to the proposed rule to accommodate the commenters' request.

(18) *Conflicts of Interest.* The first proposal required a description of procedures intended to be implemented to prevent the occurrence of conflicts of interest. It also required the identification of any food or agriculture-related business interests of all personnel intended to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, all parties responsibly connected to the certification operation, and immediate family members, that may result in a conflict of interest. Commenters stated that existing State policies should be sufficient to prevent conflicts of interest. They also stated that lists of the business interests of all inspectors, program staff, and their families are unnecessary.

We agree with the commenters that existing State policies should be sufficient to prevent conflicts of interest. However, we disagree with the commenters' assertion that lists of the business interests of all inspectors, program staff, and their families are unnecessary. At § 6515(h), the Act places responsibility for the prevention of conflicts of interest with the certifying agent. We, however, have responsibility for ensuring that the certifying agent complies with that responsibility. We believe these requirements will provide the Administrator with information essential to the identification of conflicts of interest. A stated purpose of the Act is the establishment of national standards. We believe such national standards extend to uniform conflict of

interest requirements for State and private certifying agents. Further, for conflict of interest standards to achieve their intended effectiveness, they must be uniformly applied to both State and private certifying agents. The required information is also essential to the Administrator's determination of the applicant's suitability for accreditation. As the commenters point out, States have established conflict of interest policies and procedures. Thus, the required information should be readily available for submission to the Administrator with minimal inconvenience to the certifying agent. Accordingly, we have made no changes in this proposal based on these comments. Regulations concerning conflicts of interest are found at §§ 205.501(a)(11) and 205.504(c) in this proposal.

(19) *Accreditation Prior to Site Evaluation.* Commenters expressed concern that applicants could be accredited prior to a site evaluation of the applicant's facilities and operations. Most, however, recognized the need for accreditation decisions on written materials as opposed to further delay to program implementation. A few of the commenters urged USDA to complete the site evaluations during the implementation phase. The first proposal provided that an initial site evaluation of the operation of each certifying agent must be performed for the purpose of verifying its compliance with the Act and regulations. Two restrictions concerning timing were placed on the performance of an initial site evaluation. First, the site evaluation had to be performed within a reasonable period of time after the date on which the agent's notice of approval of accreditation was issued. Second, the site evaluation had to be performed after the agent had conducted sufficient certification activities for the Administrator to examine its operations and evaluate its compliance with the general requirements for accreditation.

We never intended that a site evaluation be required prior to accreditation. While site evaluations could be conducted before approval, we believe accreditation approval without a site evaluation is appropriate. We believe that the commenters' concerns are adequately addressed by the first proposal, which provided for a well-founded assessment of the applicant's qualifications and capabilities through a sufficiently rigorous review of the application and supporting documentation. In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation would be conducted.

As noted above, a site evaluation to verify compliance with the Act and regulations would be conducted within a reasonable time period after the date on which the agent's notice of approval of accreditation was issued. Following the site evaluation, the certifying agent's accreditation would be continued provided the certifying agent is in compliance with the Act and regulations. Should it be found that the accredited certifying agent is not in compliance with the Act and regulations, the Administrator will issue the certifying agent a notification of noncompliance and afford the certifying agent an opportunity to correct the deficiencies. If the deficiencies are not corrected, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation.

We also believe that: (1) Conducting a site evaluation of a newly established certifying agent before it had begun any certification activities might not contribute information that would be useful for the Department's evaluation; (2) previously existing certifying agents also would need time to make adjustments in their operations to comply with the NOP regulations; and (3) requiring full site evaluations and peer reviews to be conducted prior to granting accreditation would further delay implementation of the Act. Accordingly, we have made no changes to the application requirements found at § 205.502 or the site evaluation requirements found at § 205.508 on the basis of these comments.

(20) *Conditional Accreditation.* Commenters suggested that the rule provide for conditional accreditation of certifying agents. We disagree with the concept of conditional accreditation. We believe accreditation before a site evaluation to be the most effective means of providing new certifying agents with the opportunity to participate in the NOP. New certifying agents need to be unconditionally accredited to sell their services to potential organic clients. Such certifying agents need organic clients to demonstrate to the Administrator their compliance with the Act and regulations relative to the certification of organic producers or handlers. Furthermore, the Act does not provide for conditional accreditation. Accordingly, the proposed accreditation program for initial accreditation provides for: (1) Review and analysis of the applicant's application and evidence of expertise and ability, (2) approval of accreditation upon determination that the applicant meets the requirements for accreditation, and (3) site evaluation to determine compliance with the Act and regulations.

(21) *Application Fees Incurred From Notifications of Noncompliance.* Commenters questioned whether a new application for accreditation, following the correction of deficiencies identified in the notification of noncompliance, would require a second application fee. The commenters stated that fees paid for the initial application should cover timely resubmission of the application after correction of deficiencies. In this proposal, we have replaced the flat fee for accreditation with an hourly user fee system, which will involve billing for actual time used in the accreditation process. Accordingly, there will be additional costs to applicants who submit a description of the actions taken to correct the deficiencies noted in the notification of noncompliance.

(22) *Peer Review Panels.* Comments were received expressing various opinions regarding the peer review panel provisions of the first proposal. First, commenters stated that peer review panels should participate in site evaluations. Prior to publishing the first proposal, the Department received some public input which also suggested the use of peer reviewers in the site evaluation process. As noted in the first proposal, we did not provide for such participation because we believed that the use of peer reviewers could pose an excessive burden on the certifying agents, would increase the costs of conducting site evaluations, and could delay site evaluations and because AMS staff are well qualified to perform the site evaluations. We have made no change to our proposal as a result of this comment.

Second, commenters stated that peer review panels should participate in the initial review of an application for accreditation. We believe this would not be an effective use of panel members' talents and expertise and would not be cost effective. We have made no change to our proposal as a result of this comment.

Third, an industry association stated that section 6516(a) of the Act clearly states that the Secretary shall consider a report, not three to five individual reports, in determining whether to approve an applicant for accreditation. We do not agree that the Act requires a single report, nor do we believe that it is usual to have consensus in peer review. We also believe that it is impractical to bring peer reviewers together for the purpose of reviewing the information provided and drafting a single report. The Administrator could convene a peer review panel meeting or

conference call if necessary. Such meeting or conference call would be conducted in a manner that would ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually. A peer review panel meeting or conference call will be held solely to give and receive information. Such meeting or conference call will not be held for the purpose of achieving consensus by the peer review panel. The written report of each panel member would reflect the particular knowledge, expertise, and opinion that its author-member brings to the panel. The Administrator will consider all points in the individual reports in making a determination as to the continued operation of the accredited certifying agent. We have made no change to our proposal as a result of this comment.

Fourth, commenters stated that the peer review panel regulations should be revised to specify what situations, other than continuation or renewal of accreditation, would trigger a peer review; that a peer review panel should be used in determining noncompliance with accreditation requirements; and that a peer review panel should be convened to review any decision of noncompliance prior to initiation of proceedings to suspend or revoke a certifying agent's accreditation. The first proposal provided that the Administrator may convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and regulations. This provision would provide flexibility for the Administrator to seek recommendations from peer reviewers at other times when it may be necessary to evaluate a certifying agent's compliance with the Act and regulations. We do not believe that it is practical or necessary to require the use of peer review panels in determining noncompliance and decisions to suspend or revoke an accreditation. We have made no change to our proposal as a result of these comments.

(23) *Purpose of Annual Reporting Requirements.* At least one commenter was confused regarding the purpose for having certifying agents submit annual reports to the Administrator. The reports would update information and evidence of expertise and ability previously submitted by the certifying agent; support any changes being requested in the areas of accreditation; describe the measures that were implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; and describe the results of the most recent inspector performance appraisals and program evaluation and adjustments to the certifying agent's operation and procedures implemented and intended to be implemented in response to the appraisals and program evaluation. The first proposal stated that this information would be reviewed by the Administrator to determine whether the certifying agent was maintaining its accreditation by satisfying the requirements of the Act and regulations and to assess the need for a site evaluation. We believe that an annual process of reviewing information submitted by certifying agents is necessary so that the Administrator can be informed of any changes in the procedures and personnel used by the certifying agents. We have made no change to our proposal as a result of this comment.

Accreditation—Additional Provisions

Upon further review of the accreditation provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Access to Records.* We have added the requirement that the records maintained by the certifying agent under the Act and regulations be made available for copying by authorized representatives of the Secretary and the applicable State program's governing State official. This addition is necessary to ensure that authorized representatives are able to obtain copies of records applicable to a review or an investigation regarding compliance with the Act and regulations. This addition, found at § 205.501(a)(9), is authorized under section 6506 of the Act.

(2) *Conflicts of Interest.* A conflict of interest regulation in the first proposal required that certifying agents prevent conflicts of interest by not certifying an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consulting services, within the 12-month period prior to the application for certification. This regulation was closely related to a second regulation which required certifying agents to prevent conflicts of interest by not assigning an inspector to perform an inspection of an operation if the inspector has or has held a commercial interest in the operation, including the provision of consulting services, within the 12 months prior to conducting the inspection. For clarification, this proposal combines the regulations at § 205.501(a)(11)(ii). This new regulation provides for excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production and handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. This regulation would permit a certifying agent to certify the operation of an employee or contractor or an employee's or contractor's immediate family member provided the employee or contractor was not used in certifying the production or handling operation.

(3) *Reporting Requirements for Certifying Agents.* The first proposal required a certifying agent to submit to the Administrator a copy of each notification of noncompliance issued simultaneously with its issuance to the certification applicant or the certified operation. It also required a certifying agent to submit to the Administrator on a quarterly calendar basis the name of each operation certified. In this proposal, we have expanded the provision to provide that certifying agents must submit to the Administrator: (1) A copy of any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance; and (2) on a quarterly calendar basis, the name, address, and telephone number of each operation granted certification. This information is needed to facilitate oversight and to ensure that we have relatively current data for responding to inquiries involving the granting of certifications by certifying agents. These changes are included in § 205.501(a)(14).

We anticipate using the data collected under § 205.501(a)(14) to establish and maintain 2 Internet databases. The first Internet database would be accessible to the general public and would include the names and other appropriate data on certified organic production and handling operations. The second Internet database would be password protected and only available to accredited certifying agents and USDA. This second database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and

suspension or revocation of certification. Certifying agents would use the second Internet database during their review of an application for certification.

(4) *Requirements for Nondiscrimination.* We have included at § 205.501(d) the provision that no private or State entity accredited as a certifying agent under subpart F shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. This regulation is consistent with USDA regulations which prohibit discrimination in its programs and activities.

(5) *Submission of Policies and Procedures.* The first proposal required an applicant for accreditation as a certifying agent to submit documents and information to demonstrate the applicant's expertise in organic farming or handling techniques, its ability to fully comply with and implement the organic certification program, and its ability to comply with the requirements for accreditation. Much of the documentation and information required involved submission of a description of a policy or procedure to be used by the certifying agent. In this proposal we have changed the requirement from submission of a description of the policy or procedure to submission of a copy of the actual policy or procedure. This will facilitate the Department's determination of an applicant's eligibility for accreditation by providing more complete information. By requiring a copy of each policy and procedure, which should already be in the possession of the applicant, rather than a description of each, we have lessened the burden on applicants for accreditation. This change is found in § 205.504 of this proposal.

(6) *Public Access to Certification Certificates.* In this proposal, we have added the requirement that certifying agents make copies of certification certificates issued during the current and 3 preceding calendar years available to the public. Such documents may be useful to consumers wishing to verify that an operation is certified to produce and label agricultural products as organic. Copies of certification certificates will be especially valuable in assisting handlers in assuring that the products they receive labeled as organic were produced and handled by certified organic operations. This requirement is found at § 205.504(b)(5)(i).

(7) *Submission of Residue Testing Procedures.* We believe that applicants for accreditation should provide evidence of expertise and ability in meeting the sampling and residue testing requirements of these regulations. Therefore, we have added the requirement that applicants for accreditation submit a copy of the procedures to be used for residue testing. This requirement is found at § 205.504(b)(6). Residue testing requirements are found at § 205.670.

(8) *Elimination of Section on Confirmation of Accreditation.* We have amended the section on approval of accreditation by adding the duration of accreditation provision formerly included in the first proposal's section on confirmation of accreditation. We have also eliminated the section on confirmation of accreditation. We have taken this action to eliminate the confusion created by having a section on approval of accreditation and a section on confirmation of accreditation.

(9) *Denial of Accreditation.* We have amended the denial of accreditation regulations and eliminated the section on denial of confirmation of accreditation. We have taken this action to eliminate the confusion created by having a section on denial of accreditation and a section on denial of confirmation of accreditation. We have added to the denial of accreditation regulations that a notification of noncompliance can be issued based on the findings of a site evaluation.

Under the first proposal's denial of accreditation regulations, the Administrator could institute proceedings to deny accreditation to an applicant who did not correct the deficiencies noted in a notification of noncompliance within the time specified. In this proposal, we have amended these regulations to provide that the Administrator will provide the applicant with a written notification of accreditation denial or begin proceedings to suspend or revoke the certifying agent's accreditation if accredited prior to a site evaluation. Such action will be taken when the applicant fails to correct the deficiencies, report the corrections by the date specified, or file an appeal by the date specified in the notification of noncompliance.

We have also clarified that an applicant who has received written notification of accreditation denial or had its accreditation suspended may apply for accreditation again at any time. Additionally, we have provided that a private certifying agent whose initial accreditation is revoked following an initial site evaluation will be ineligible for accreditation for a period of not less than 3 years following the date of such determination. This period of ineligibility is consistent with section 6519(e) of the Act. These changes are included in § 205.507.

A certifying agent accredited prior to an initial site evaluation whose site evaluation reveals that the certifying agent is not properly adhering to the provisions of the Act or these regulations will be subject to suspension of its accreditation. A private certifying agent accredited prior to an initial site evaluation who's site evaluation reveals that the certifying agent has violated the provisions of the Act and these regulations or that falsely or negligently certifies any production or handling operation that does not meet the terms and conditions of this national organic certification program as an organic operation will be subject to revocation of its accreditation. Section 205.660(b) of subpart G provides that the Secretary may initiate suspension or revocation proceedings against a certified operation upon initiation of suspension or revocation proceedings against or upon suspension or revocation of the certified operation's certifying agent's accreditation.

(10) *Peer Review Panels.* We have removed the provision which provided that the Administrator may convene a peer review panel at any time for the purpose of evaluating an applicant for accreditation or a certifying agent's activities under the Act and regulations. This change has been made because peer review panels will only be used to assist in the evaluation of applicants for accreditation, amendment to an accreditation, and renewal of accreditation.

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

Proposal Description

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as ''organic'' or ''made with organic (specified ingredients).'' It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with

annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

The first category of the National List includes synthetic substances allowed for use in organic crop production. The second category includes nonsynthetic substances prohibited for use in organic crop production. The third category of the National List includes synthetic substances allowed for use in organic livestock production. The fourth category includes nonsynthetic substances prohibited for use in organic livestock production. The fifth category of the National List includes nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients).'' The final category of the National List includes nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients).'' This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

National List (General)

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA authorizes the NOSB to develop and forward to the Secretary a Proposed National List and any subsequent proposed amendments. In March 1995, the NOSB initiated a petition process to solicit public participation in identifying specific materials to be added to the National List. The NOSB convened a Technical Advisory Panel (TAP) to review substances identified in the petition process and made extensive recommendations on a Proposed National List during its meetings in 1995 and 1996. In 1999, the NOSB selected materials left from the original petition process to authorize a second round of TAP reviews. The NOSB used these updated TAP reviews to make additional recommendations on the Proposed National List at its October 1999 meeting. With the exception of four substances on which the Secretary did not concur with the NOSB recommendations and minor formatting changes, the National List in this proposal corresponds to the recommendations on allowed and prohibited substances made by the NOSB. The National List in this proposal has also been developed in consultation with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Food Safety Inspection Service (FSIS) of USDA. Additionally, we have made changes in response to public comment received on the first proposal.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA establishes safety regulations on approved and prohibited uses of substances in food production and processing. FSIS has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or ingredients take precedence over the approved and prohibited uses specified in this proposal. Any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. Use-of-substance requirements are proposed by FDA and FSIS in rulemaking actions and are frequently updated with revised use requirements. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFD&CA). Animal feed labeling requirements are published in 21 CFR part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR parts 510–558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances (GRAS), substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR parts 570–571, 21 CFR part 573, 21 CFR part 582, 21 CFR part 584, and 21 CFR part 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO Official Publication, which is updated annually.

National List—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Genetically Engineered Organisms (GEO's).* To solicit public comment on the use of genetically engineered organisms in organic production and handling, we included two such materials on the National List in the first proposal. As discussed in Production and Handling—Subpart C, we received many thousands of comments opposing the use of substances or organisms produced through genetic engineering in organic production and handling. Many commenters expressed strong concerns that GEO's do not meet current consumer expectations of organic agriculture or an organically produced product. They stated that existing national and international organic certification standards clearly and consistently prohibit GEO's. Accordingly, this proposal prohibits GEO's and their derivatives and the products of GEO's and their derivatives in any product or ingredient that is sold, labeled, or represented as organic. As a result of the prohibition, the National List does not contain any materials derived from GEO's.

(2) *Inclusion of Substances not Recommended by the NOSB.* The first proposal allowed some synthetic substances in organic crop production and handling that the NOSB had not included on the proposed National List. Citing the statutory requirements of the OFPA, commenters were overwhelmingly opposed to adding substances to the National List that had not been recommended by the NOSB. Every substance on the National List in this proposal was favorably recommended by the NOSB.

With four exceptions, the National List included in this proposal contains every substance that the NOSB recommended to allow in organic production and handling. The Secretary has not accepted the NOSB recommendations to allow sulfur dioxide in the production of wine labeled as ''made with organic grapes.'' Additionally, the Secretary has not concurred with the NOSB recommendation to allow the antibiotics, Streptomycin and Terramycin, in organic crop production or to allow livestock producers to administer synthetic Oxytocin for approved organic veterinary practices. The Secretary decided not to add sulfur dioxide to the National List because its use produces sulfites, which are

prohibited in the OFPA. Streptomycin and Terramycin were not added to the National List for use in crop production in order to be consistent with this proposal's prohibition on the use of all antibiotics in animal production. The Secretary's decision not to allow livestock producers to administer synthetic Oxytocin is based on extensive public comment that opposed the use of animal drugs including hormones in organic livestock operations. Many certifying agencies have allowed producers to administer Oxytocin to animals that experience severe complications resulting from labor. While most of the public comment strongly opposed the use of synthetic hormones in organic dairy production, Oxytocin has some uses that do not involve lactation but are instead related to an animal's postpartum survival. Not allowing Oxytocin in organic operations is responsive to the public comment opposing the use of synthetic hormones but does preclude the use of an animal medication that some producers have previously been able to use in emergency situations.

(3) *Prohibited Nonsynthetic Substances.* The National List in the first proposal contained no prohibited nonsynthetic (natural) substances. Many commenters requested that the four nonsynthetic substances which the NOSB proposed to prohibit be added to the National List. We agree with this position, and this proposal lists ash from manure burning, mined sodium fluoaluminate, strychnine, and tobacco dust as natural substances that are prohibited in organic crop production and handling. In addition, we have included arsenic and lead salts on the National List of prohibited natural substances in accordance with provisions of the OFPA.

(4) *Annotations on National List Substances.* The National List in the first proposal did not include all of the annotations originally developed by the NOSB for the materials it recommended to include on the National List. The OFPA stipulates that when basing the National List upon the NOSB's recommendations, the Secretary shall include ''an itemization, by specific use or application,'' of each synthetic substance permitted or natural substance prohibited. This itemization, commonly known within the organic industry as an annotation, has been used by existing State and private certification agents to regulate the use of allowed materials. Annotations can establish allowable sources or procedures for obtaining a substance, specify the crops or conditions for which it may be applied, establish use restrictions based on environmental monitoring, or create other conditions to govern the use of a substance.

Many commenters stated that removing annotations diminished the NOSB's role in advising the Secretary on the content of the National List. Commenters also stated that annotations are essential for ensuring that substances are used in a manner which is consistent and compatible with a system of organic production and handling. Considering how annotations have been applied in regulating the use of allowed substances by State and private certifying agents, we have incorporated every feasible NOSB-proposed annotation in this proposal.

(5) *Incidental Additives.* The first proposal stated that a nonagricultural synthetic substance occurring as an incidental additive, including a processing aid, could be used in organic production and handling without having to be added to the National List. This position was based on FDA and FSIS regulations which require that active ingredients, but not incidental additives, appear on a product label. Because incidental additives were not active ingredients in organically processed food under these regulations, the first proposal maintained that they were not prohibited by the OFPA and would not need to be added to the National List.

Thousands of commenters responded with varying opinions on this subject. Many commenters approved of the proposed approach, generally stating that processing aids are essential and needed for most agricultural products. These commenters felt that eliminating their use entirely would greatly limit handlers' ability to produce a wide variety of organic products. However, other commenters strongly opposed allowing the use of any nonagricultural synthetic substance that had not been petitioned, reviewed, and recommended by the NOSB; published for comment in the **Federal Register**; and then added by the Secretary to the National List. Some commenters protested the use of any synthetic incidental additives in organic handling operations. They stated that their use is not consistent with the principles of organic agriculture and that consumers currently do not believe that such aids and additives are used in organically processed products.

Prior to the first proposal, the NOSB reviewed this issue and recommended allowing both synthetic and nonsynthetic incidental additives in processed organic products. The NOSB's 1995 recommendation stated that nonsynthetic, nonagricultural products used as ingredients, processing aids, or incidental food additives should be categorically allowed in organically processed products unless specifically prohibited and that synthetic, nonagricultural products should not be used as ingredients, processing aids, or incidental food additives unless specifically included on the National List. The NOSB applied these recommendations to processed foods labeled ''organic'' and ''made with organic (specified ingredients).'' However, the OFPA does not allow the categorical allowance for nonsynthetic, nonagricultural products. Section 6510(a)(4) of the OFPA requires that any nonorganically produced ingredient added to an organic product must be included on the National List.

The NOSB revisited this issue at its February 1999 meeting when it adopted criteria for accepting (adding to the National List) a synthetic processing aid or adjuvant. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. To review the adopted criteria, the public can visit the USDA NOP website: www.ams.usda.gov/nop/nosbfeb99.html or write Program Manager, Room 2945 South Building, U.S. Department of Agriculture, AMS, Transportation and Marketing Programs, NOP, PO Box 96456, Washington, DC 20090–6456. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted criteria do not supercede the criteria contained in the OFPA, or replace FDA's authority to regulate food additives.

We are proposing that to be used in or on a processed product labeled as ''organic'' or ''made with organic (specified ingredients),'' a nonagricultural substance, whether synthetic or nonsynthetic, must be included on the National List. This position supports the NOSB recommendation that synthetic substances be allowed in organic processed foods but incorporates the National List requirement reflected in public comment. We have divided the materials on this list (§ 205.605) in the current proposal to reflect the recommended distinction made by the NOSB between synthetic and nonsynthetic substances. This distinction does not affect how the substances may be used. We recognize that many commenters, basing their argument on the OFPA, objected to allowing any synthetic substances in processed organic products. However, we believe that the OFPA does allow

synthetic substances, when added to the National List, to be used in this manner. The criteria utilized by the NOSB for evaluating processing aids and adjuvants are very restrictive and, if applied to all incidental additives, should minimize the number of substances added to the National List.

(6) *Inert Ingredients in Formulated Products.* The first proposal addressed the presence of synthetic inert ingredients in formulated products used as production inputs in organic crop or livestock operations. Formulated products are multiingredient compounds including pesticides, fertilizers, and animal drugs and feeds. In accordance with the OFPA, we proposed that a formulated product containing an inert ingredient could be used, provided that the substance did not appear on EPA's List 1 as an Inert of Toxicological Concern. We also prohibited the use of synthetic inerts not on EPA List 1 if the substance was also used as an active ingredient that had not been added to the National List. To review or to receive the most current listing of the EPA Inerts, the public can visit EPA's Internet home page at http://www.epa.gov/opprd001/inerts/lists.html, or write to Registration Support Branch (Inerts), Registration Division (Mail Code 7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

The first proposal interpreted the statutory prohibition on EPA List 1 inerts as allowing the use of synthetic inert ingredients that were not specifically prohibited. This allowed the use of products containing synthetic inert substances (provided that they were not also used as active substances) included on the other EPA inert lists: List 2, Potentially Toxic Inerts; List 3, Inerts of Unknown Toxicity; and List 4, Inerts of Minimal Concern. We also applied the term, ''inert,'' to all nonactive ingredients contained in any formulated product used in organic production. This meant that the nonactive ingredients in animal feeds (fillers or additives), animal drugs (excipients), and fertilizers (carriers or adjuvants) would only be prohibited if they were classified by the EPA as List 1 inerts.

We received many comments stating that our restrictions on inert ingredients were too permissive and would result in many traditionally prohibited materials being used in organic production. Commenters stated that the statutory prohibition on EPA List 1 inerts did not imply that all other inerts should be allowed and argued that the NOSB had the authority to prohibit additional substances. Citing the uncertainty associated with EPA List 2 (potentially toxic) and EPA List 3 (unknown toxicity) inert ingredients, they questioned how such substances could satisfy the criteria in OFPA for adding synthetic substances to the National List. Commenters also opposed expanding the definition of inert to include nonactive ingredients in all formulated products. They stated that the EPA classifies only those inerts used in pesticides, and that many of the substances routinely used in other types of formulated products were not subject to review. Therefore, substances not used in pesticides would not appear on any EPA list and would be allowed. Finally, commenters cited the disparity between the allowance for synthetic inert ingredients in the first proposal and the more restrictive substance review procedures used by existing organic certifying agents.

The NOSB responded to the provisions for inert ingredients contained in the first proposal. At its meeting in March 1998, the NOSB stated that synthetic compounds should not be allowed in production inputs unless they appear on the National List. In February 1999, the NOSB voted to prohibit EPA List 1 and 2 inerts, prohibit EPA List 3 inerts unless specifically allowed by the NOSB, and allow EPA List 4 inerts unless specifically prohibited. The NOSB also recommended full disclosure of all ingredients in formulated products, called for an expedited review of EPA List 3 inerts currently in common use in organic production, and endorsed an 18-month phase-out period for EPA List 3 inerts not ultimately allowed.

In this proposal, only EPA List 4 inerts are allowed as ingredients in formulated products used in organic production. This would not include varieties of EPA List 4 substances such as corn starch, lecithin, or citric acid that are the product of excluded methods. Additionally, the term inert is restricted to nonactive ingredients in pesticides. Synthetic nonactive ingredients in formulated products used as production inputs, including fertilizers, animal drugs, and feeds, must be included the National List. While the OFPA prohibits using a fertilizer containing synthetic ingredients or a commercially blended fertilizer containing prohibited materials, the requirement does not apply to synthetic substances included on the National List. The NOSB recommended and the Secretary concurs that certain synthetic substances used in fertilizer-formulated products should be included on the National List. We have retained the provision from the first proposal prohibiting the use of any formulated product containing a EPA List 1 Inert. Using the criteria established in the OFPA for evaluating synthetic substances, the NOSB may review inert ingredients on EPA List 2 or 3 as well as other synthetic, nonactive substances used in formulated products for inclusion on the Proposed National List it forwards to the Secretary.

We recognize that inert ingredients in pesticides and similar substances in other formulated products pose one of the most problematic examples of the use of synthetic materials in organic production. For example, verifying the use of inerts and similar substances such as fillers, carriers, additives, and excipients has been difficult because they are not required to appear on ingredient labels, and formulators typically treat product formulas as confidential information. At times, certifying agents have been unable to determine the exact composition of formulated products proposed for use in organic production. In other instances, organic producers have applied formulated products containing inert ingredients and similar substances that are not specifically allowed. We are challenged with balancing standard practice with the strict statutory requirement that producers and handlers apply only those synthetic substances added to the National List. As sanctioned by OFPA, synthetic substances can be used in organic production as long as they appear on the National List. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

Two principles will be essential for responding to this challenge: greater disclosure of the contents of formulated products and an expedited review of inert ingredients and other nonactive substances. The OFPA recognized the need for disclosure by requiring the NOSB to work with formulators to obtain a complete list of ingredients in their products. The NOSB has initiated this work, and its effort is ongoing as of the date of this publication. It is our understanding from the comments, hearings, and information considered by the NOSB that the organic industry has made considerable progress on disclosure of inert ingredients since the passage of OFPA. Formulators have responded to the incentive to provide products using EPA List 4 inert ingredients, and certifying agents have

gained greater access to information on product composition. EPA has expressed its willingness to expedite the review of its List 2 and 3 inerts, which the NOSB identifies as particularly important in formulated products widely used in organic operations. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as the NOSB's primary activity during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances which are essential to organic production and handling.

We recognize that more work is needed for this policy to satisfy the needs of organic producers and handlers, product formulators, and consumers. We are requesting comment on the proposed requirements for inert ingredients in formulated products. We are sensitive that an abrupt prohibition on synthetic substances which may have knowingly or unknowingly been used in the past but which are not added to the National List may disrupt many well-established and accepted production systems. However, our assessment is that the benefits of a clear policy consistent with the OFPA, NOSB recommendations, and public comment outweigh the costs. The net effect will be greater consumer confidence in USDA's organic label and more products that are tailored to the needs of organic producers.

(7) *Use of Veterinary Medicines.* The OFPA prohibits certain routine uses of veterinary medications (specifically subtherapeutic doses of antibiotics) but allows their administration in the presence of illness. The first proposal added antibiotics to the National List because their use had been evaluated and approved by applicable regulatory agencies, pursuant to FDA requirements, and because they had to be included on the National List to be used in organic livestock production.

We received many comments opposing the use of antibiotics in organic livestock production. Commenters expressed general concern over microbial resistance to antibiotics and expressed a desire to source food products without antibiotics. This proposal removes antibiotics from the National List of approved synthetic substances for livestock use.

(8) *Removal of Substances from the National List.* The first proposal outlined a petition process for amending the National List and included an extensive list of information to be provided for reviewing a substance. Some commenters recommended that this section be amended to include procedures for deleting substances from the National List. The OFPA and the first proposal indicated that the NOSB would review substances added to the National List at least on a 5-year basis and recommend to the Secretary any substances that should be removed. We concur with commenters that removal of a substance should not have to wait for such a review cycle. Thus, a petition to remove a substance from the National List may be filed at any time. The information contained in the petition for removal of a substance will be provided by AMS upon request. The NOSB will evaluate substance removal petitions and forward a recommendation to the Secretary. Commenters suggested that any changes to the National List be published in the **Federal Register** for public comment. All proposed changes to the National List will be published in the **Federal Register**.

(9) *Use of Sulfur Dioxide.* The first proposal allowed the use of sulfur dioxide in crop production and as an ingredient in or on organic processed products. The NOSB had recommended that sulfur dioxide be permitted in the processing of organic wine and for smoke bombs used underground to control rodents. Numerous commenters opposed the use of sulfur dioxide in organic wine because its use produces sulfites, which are prohibited in the OFPA, as a by-product. We concur with the commenters and further believe that the trend in the organic industry, as evidenced by the California Department of Food and Agriculture's Preliminary Organic Materials List of September 1998, is to prohibit all uses of sulfur dioxide except in underground rodent control. Therefore, we are proposing to allow sulfur dioxide for underground control of rodents and to prohibit its use as an ingredient in or processed food including the production of organic wine.

National List—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *New Additions to the National List.* During the October 1999 meeting, the NOSB reviewed substances and made new recommendations to the Proposed National List. The Secretary concurs with the recommendations from that meeting and this proposal adds those substances with the applicable annotations to the National List. These substances are: Potassium Bicarbonate (205.601(d)), Glycerin (2005.603(a)), Phosphoric Acid (205.603(a) and 205.605(b)), Ivermectin (205.603(a)), Chlorhexidine (205.603(a)), and Ethylene (205.605(b)). This proposal establishes conditions that allow producers to administer the parasiticide Ivermectin to breeder stock and dairy stock in organic livestock operations. Treating organically managed slaughter stock with Ivermectin is prohibited. These provisions are based on the recommendations developed by the NOSB at its October 1999 meeting. The NOSB's recommendations from that meeting were derivative of many years of work addressing how to establish and enforce the conditions allowing use of synthetic parasiticides. The OFPA identifies livestock parasiticides as a category of substances which may be included on the National List and also prohibits the use of synthetic internal parasiticides on a routine basis. The determination of what constitutes a routine basis for parasiticide use has been challenging given the diversity of animals, production systems, and environmental factors which are covered by a national organic standard.

In this proposal, the conditions under which Ivermectin may be used apply to the health care history of the animal prior to treatment and the certification of products derived from the animal after treatment. The pretreatment conditions are designed to ensure that the producer is using a comprehensive management system to prevent the introduction and transmission of parasites among the animals in his or her care. Producers must document in their organic system plan preventative practices such as quarantine and fecal exams for all incoming stock, appropriate pasture rotation and management, culling of infested livestock, and vector and intermediate host control. A producer may administer an allowed synthetic parasiticide only after all applicable management practices and nonsynthetic treatments have been employed. A producer must receive the approval of their certifying agent before using a synthetic parasiticide. In collaboration with the NOSB, we will be developing program manuals detailing preventive management practices for specific livestock species to assist producers and certifying agents in determining when the use of synthetic parasiticides is allowable.

This proposal also contains provisions addressing the posttreatment condition of livestock which are administered Ivermectin. These conditions are included as an

annotation to Ivermectin on the National List and are consistent with the requirements contained in § 205.238(b)(1)(2) of the regulatory text for administering any allowed synthetic parasiticide. In compliance with the recommendations of the NOSB, we are proposing that a producer may not administer Ivermectin to breeder stock during the last third of gestation if the progeny is to be sold, labeled, or represented as organically produced. Additionally, a producer must observe a 90-day withdrawal period before selling milk or milk products produced from an animal treated with Ivermectin as organically produced. The Food and Drug Administration exercises responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals.

Ivermectin is the first synthetic parasiticide that the Secretary has proposed adding to the National List, and allowing its use could significantly affect organic management practices. The FDA has approved 18 animal drugs containing Ivermectin that are labeled for use on one or more animals including beef and dairy cattle, sheep, swine, and several minor species. A total of 11 of these drugs are not covered by this proposed rule: three have additional synthetic active ingredients not on the National List and eight others are labeled for nonfood uses. (They are used on horses not for food use, dogs, and cats.) While there are no approved uses of Ivermectin on lactating dairy animals, the remaining seven food-use products could be administered to breeder stock and dairy stock either prior to lactation or during a dry period.

Future NOSB meetings will consider new proposals of substances to be added to the National List.

(2) *Petition Process to Amend the National List.* We are modifying the contents of the petition for amending the National List that was contained in the first proposal. We are proposing that any person requesting a change in the National List should request a copy of the petition procedures from the NOP Program Manager. The procedures will include a list of information that has to be provided for consideration of a change in the National List. Under the provisions in the first proposal, the NOP would be required to go through rulemaking every time it sought to update contents of the petition. Under this proposal, the NOP will amend the requirements of the petition process and publish the changes in the **Federal Register**. This revised process will help to expedite amending the National List and keep the National List more current. We anticipate that amendments to the National List will be made on an annual basis, depending upon the number of substance petitions filed. Substances petitioned for inclusion onto the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. All amendments to the National List will be published for comment in the **Federal Register**.

State Organic Certification Programs

The Act provides that each State may implement a certification program for producers and handlers of agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of this regulation. Each State organic certification program must be approved by the Secretary. A State organic certification program's organic standards and requirements cannot exceed these National Organic Program (NOP) regulations unless the State petitions for, and the Secretary approves, more restrictive requirements. The sections covering State programs, beginning with § 205.620, establish: (1) The requirements for a State organic certification program and amending such a program; and (2) the process for initial approvals of programs and program amendments. A process for review and approval of a State's organic certification program every 5 years will be addressed in subsequent rulemaking.

Proposal Description

There are a wide variety of organic certification programs now operating in different States. Approximately 31 States currently have, or are developing, their own State organic certification programs. At least 13 of those use State government agencies or contracted private certifying agents to certify organic operations in the State. Thus, at least 19 States do not have State organic programs and approximately 37 States do not have State Government or State-designated private certifying agents. Under this proposal, States may utilize these NOP standards and requirements and not have State oversight or responsibility for administration of the NOP in the State. On the other hand, a State may petition the Secretary for approval to add its unique State requirements to the NOP and agree to administer the national program in the State.

Requirements of a State Organic Certification Program. Under the Act and the NOP, a State, through the State program's governing State official, must submit to the Secretary a copy of the proposed State organic certification program. The governing State official must submit an affidavit or memorandum of understanding agreeing to meet the 11 general requirements of an organic program, as specified in section 6506(a) of the Act. Specifically, the governing State official must agree to: (1) Require that product sold or represented as organic must be produced and handled only by certified organic operations; (2) require that participating organic producers and handlers establish organic plans for their operations; (3) allow certified producers and handlers to appeal adverse decisions under appeal provisions of these regulations; (4) require that certified operations certify annually that they have complied with the NOP; (5) provide for annual on-site inspections of certified operations by certifying agents; (6) require periodic residue testing by certifying agents; (7) provide for appropriate and adequate enforcement procedures which are consistent with the NOP; (8) protect against conflict of interests as specified in these regulations; (9) provide for public access to certification documents; (10) provide for collection of reasonable fees; and (11) require other terms and conditions as may be established by the Secretary. The NOP will assume these responsibilities in States that do not have an approved State organic certification program.

Supporting materials must be submitted addressing these general requirements, including such documentation as: authorizing State statutes, program goals and objectives, a description of the State's organic program office, codified compliance and appeals processes, and other information as may be requested by the Secretary. Written material must assess the State organic certification program's ability and willingness to administer the 11 general requirements for organic programs. Administration of these general requirements may require development of a unique working relationship between the State organic program and the NOP.

With the approval of its State organic certification program, the State must assume responsibility for administration of these 11 general requirements and any approved, more restrictive requirements in the State. For instance, a State's responsibilities will include oversight of certified organic production and handling operations to ensure that

products sold or represented as organic are produced and handled pursuant to these regulations. A State's organic certification program must include noncompliance and appeals procedures similar in force and effect to those outlined in the Compliance and Appeals provisions of this subpart. We expect that every State has in place official compliance procedures and formal appeal procedures which are used to enforce the State's regulatory programs. Those procedures should provide opportunity, as do the procedures in this subpart, for entities that may not be in compliance with State regulations, to come into compliance with those regulations. Such procedures should be clearly addressed in the State's organic certification application.

A proposed State organic certification program and any proposed amendment to such a program must be approved by the Secretary prior to being implemented by the State. A State may have other organic State sponsored projects, such as research and promotion programs, tax incentives, or transition assistance for organic producers within the State. Such programs would not be subject to the Secretary's approval, provided they do not conflict with the purposes of the Act.

Under certain circumstances, a State organic program may have more restrictive requirements in the State than corresponding NOP requirements for production and handling of organic product and certification of organic production and handling operations. These more restrictive requirements must be based on unique environmental conditions or specific production or handling practices particular to the State or portion of the State. Any environmental condition cited in the proposed amendment must be of a nature that implementation of these NOP regulations will be insufficient to correct the condition. The environmental condition must necessitate use of more restrictive practices or requirements rather than the corresponding practices and requirements provided in these regulations. Any such condition that is limited to a specific geographic area of the State will be required of organic production and handling operations active only in that geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for appropriate organic producers and handlers in the State or area of the State.

We do not expect that a State's request for more restrictive requirements will cover a wide range of organic production and handling standards. Rather, the increased requirements are likely to be limited to a specific production or handling practice or a more restricted use of approved National List substances to address needs or critical conditions in a specified geographic area(s). For instance, to protect an endangered lake or estuary, a State may have more restrictive buffer zone requirements than are provided in this regulation. Such a State may request that its more restrictive buffer zone requirements be established as the minimum buffer zone requirements of this regulation.

A State's more restrictive standards will not be applied to production and handling activities outside the State or a specified geographic area in the State. Further, the more restrictive standards do not apply to marketing of organic product and, thus, will not be used to restrict access of organic product produced in other States.

Section 205.621 provides that a State program's governing State official will submit to the Secretary a copy of a proposed State organic program or request for approval of any substantive amendment to a State's approved program.

State Program Approval Process. We envision the request and approval process will occur during the period between publication of the final rule and the projected effective date of the this national program (which will be announced in the final rule). Because requirements of a State organic program cannot exceed the requirements of this program unless warranted by unique conditions in the State, some State organic programs currently in effect may elect to discontinue their programs when the NOP becomes effective. Those programs simply will not request approval of their programs and their State organic requirements, in effect under the State program, will be superseded on the effective date of the NOP. State organic certification programs which seek approval of their programs will submit the required material and continue operations until the effective date of the NOP. We envision that all approved State organic certification programs will become effective under the NOP on the day the program becomes effective. A State wishing to establish a new State organic certification program under the NOP may submit the State program request and supporting material at any time. New programs submitted after this program becomes effective will be subject to the same review and approval process.

The submitted copy of the State organic certification program must be in its final form and ready for implementation. It cannot be altered by the State during the review process unless the change is cleared with the Secretary.

Amendments to State Programs. For amendment of a State organic program, the State program's governing State official must submit a copy of the proposed amendments and justification for them. The supporting material must document the unique environmental or ecological conditions or production practices in the State that necessitate use of more restrictive organic requirements. The supporting material must also explain how the more restrictive requirements will address the environmental condition. Likewise, the supporting material must explain how the increased requirements are better suited to agricultural conditions in the State.

Because State organic certification program requirements cannot be less restrictive than NOP requirements, any amendment to lower such requirements could only entail a relaxation of a more restrictive requirement previously approved by the Secretary. Thus, an amendment to relax a State program's requirement also must be reviewed by the Secretary. A decrease in a State organic certification program's more restrictive requirements must be justified, based on documented changes in the unique conditions or practices which warranted the increase in requirements.

Written materials supporting an amendment must assess how the more restrictive requirements further the purposes of and are consistent with the Act and these regulations. The written material should acknowledge that the more restrictive State requirements will not be used to limit or restrict access of organic products produced in other States or foreign countries to markets in the State. Also, supporting materials must explain how the amended requirements would affect the State program's governing State official's ability to administer the 11 general requirements. A request to relax a requirement also must address these issues.

The Secretary will review each State's application based on how closely it complies with the purposes and intent of the Act and the provisions of the NOP and how well its administrative capabilities and processes match up with the needs of the State's program.

The Act provides that the Secretary's review and determination of a new State organic certification program or a

program amendment will take no more than 6 months. AMS will notify the public upon approval of each State program. The public information will be made available to national agricultural news media and to all news media in the State. AMS will identify, among other things, any more restrictive certification requirements that are included in the approved State program.

A denial of a new program or program amendment will include a written explanation of why the proposal is denied and what changes will be needed for the program to be approved. The State may implement needed changes and submit a new program or program amendment.

Section 205.622 establishes that State organic certification programs will be reviewed at least once every 5 years by the Secretary and that a determination will be made within 6 months of the anniversary date as to continuation of the State organic certification program. We will issue appropriate procedures regarding this requirement at a later date, after AMS and the States have had an opportunity to administer the NOP and State programs.

State Programs—Changes Based On Comments

There are no changes based on comments.

State Programs—Changes Requested But Not Made

(1) *Allowing more restrictive State standards.* About a third of those commenting on State organic certification program provisions complained that the first proposal gave USDA complete control over State organic standards. A few suggested that a State with higher organic requirements should be able to prohibit the in-State sale of products certified only to the NOP or other State organic program requirements. Another commented that the NOP should ''defer'' to other State organic certification programs with higher standards.

While paragraph (b)(1) of section 6507 of the Act provides that States may establish more restrictive organic certification requirements, paragraph (b)(2) establishes parameters for those requirements. More restrictive State organic program requirements must: Further the purposes of the Act; be consistent with the Act; not discriminate against other States' agricultural commodities; and be approved by the Secretary before becoming effective. As noted above, we expect that a State's more restrictive requirements are likely to cover specific production or handling practices such as more restricted use of approved National List substances or farming practices to address a State or area's particular environmental conditions.

The Secretary must employ some consistent and common criteria for approving States requests for more restrictive State organic programs. The criteria for establishing such requirements must be consistent with the purposes of the Act. We believe the need to preserve, protect, and enhance unique environmental or farming conditions is a common criterion for all States. We believe such criteria are consistent with the stated goals of most, if not all, State organic programs and organic trade and farming organizations.

The more restrictive standards will not be applied to production and handling activities outside the geographic area of the State. Further, the more restrictive standards do not apply to marketing of organic product and, thus, will not be used to restrict access of organic product produced in other States. Clearly, prohibiting the sale of other States' products is prohibited by the Act as well as other national laws covering interstate commerce in the United States. If some States were to restrict access to State markets, the purposes and the benefits of the national program would be lost.

Discriminatory marketing practices are prohibited under section 6507(b)(2)(c) of the Act. Thus, the purpose of more restrictive State organic requirements cannot be, as the commenters suggest, to allow claims of more organic or purer product. States will not be able to promote their products as being more organic because their products were produced under more restrictive State requirements. More restrictive State organic requirements will be authorized only as needed to respond to special environmental or production conditions in the State which necessitate more restrictive requirements. Any State's request for less restrictive or lower organic standards than are required under this program will not be approved by the Secretary.

(2) *Treatment of private and State certifying agents.* Some private certifying agents commented that the first proposal would permit accredited State certifying agents to establish more restrictive standards than these regulations but prohibit private certifying agents from establishing their own more restrictive requirements. Under this program, State certifying agents will not unilaterally establish organic standards or requirements in a State. A State program's governing State official may, upon approval of the Secretary, establish a State organic certification program as an entity of the State's department of agriculture or other similar State government agency. The Act provides this authority to the State government and does not provide similar authority to private certifying agents. Private certifying agents are not government entities and have no official regulatory or administrative authorities over agricultural activities in the State. State certifying agents as well as private certifying agents will act as service providers, certifying to national and, where applicable, to particular State organic requirements.

Again, commenters appear to miss an essential point of this national program. The only mandatory organic standards and requirements are those of the NOP and the unique requirements approved for a State organic certification program by the Secretary. A private certifying agent may believe its more restrictive requirements result in a more organic or purer product and may want to certify producers and handlers only to those requirements. However, neither State certifying agents nor private certifying agents will be able to require that client operations or organic product be certified to more restrictive standards than the standards of this program or approved State standards. The only other more restrictive requirements that may be certified to may be requirements made at the request of handlers or manufacturers who are purchasing the organic product or ingredient. For example, a producer could request a certifying agent to certify certain production practices required for export to a foreign manufacturer. Such certification can be made only at the request of the producer or handler being certified. Both State and private certifying agents may certify to the requested more restrictive contract requirements, provided those more restrictive requirements are consistent with these regulations and provided the certifying agents have the necessary technical qualifications to carry out the certification.

Similarly, one commenter stated that the NOP should not prevent a private certifying agent from having and advertising its own higher organic standards. While a private certifying agent may have the capability to certify to certain higher organic requirements, a handler certified by the certifying agent may not claim on product labels or in market information that its products are more organic, purer, or better than product certified by other certifying agents or State organic programs.

In this regard, certifying agents, whether they are State or private certifying agents, may not use different seals, logos, or other identifying marks to distinguish between organic operations certified to NOP requirements and a State's approved more restrictive requirements, the certifying agent's preferred requirements, or the client's requested higher requirements. We believe that if certifying agents were allowed to use more than one seal or identifying mark, based on various standards certified to, the marketplace would be inundated with a variety of different certifying agent seals, logos, and identifying marks. This would add to consumer confusion, complicate the marketplace, and jeopardize benefits of this program.

(3) *Private certifying agent concerns.* Several commenters expressed concern that private certifying agents are at a disadvantage vis-a-vis State certifying agents. They stated that a State organic program or a State certifying agent could initiate policies that would limit the activities or effectiveness of private certifying agents. However, this proposed program does not alter the current situation in that State and private certifying agents operate in the same States. If a requested State organic certification program proposes a requirement or procedure that will have a negative affect or discriminate against private certifying agents operating in the State, the Secretary will not approve the requirement or procedure.

Some commenters asked whether these national regulations will affect a State's accreditation of private certifying agents operating in the State. A few believe that States should be allowed to continue or establish separate accreditation programs for private certifying agents.

We believe accreditation of certifying agents is a core responsibility for USDA. Establishment of a single national accreditation program is an essential part of the NOP. States will not accredit private certifying agents. As stated elsewhere in this proposal, any accreditation responsibilities of a State's current organic certification program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official or designee charged with compliance oversight under the State program may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That authority is the sole responsibility of the Secretary.

If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities must include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State, and to monitoring their compliance with accreditation requirements.

(4) *Public comment on State applications.* One commenter suggested that USDA publish for comment in the **Federal Register**, a summary of each State's proposed organic program and any requested program amendments. The commenter claimed that an approved State organic certification program will effectively substitute the State's program for the NOP in the State. Thus, the commenter contends, those proposed State programs and program amendments should be made available for public comment. After consideration of the implications of the comment, we do not believe that the **Federal Register** notification process is the proper venue for receiving comments on a proposed State program which is applicable only to residents and business entities in the State. We assume that the governing State official is submitting the request on behalf of the organic producers and handlers in the State. Further, the appropriateness of the State's requested more restrictive requirements should stand on the merits of each proposal and not on whether commenters in other States believe the proposed requirements are warranted. Certified organic producers and handlers outside the State will not be subject to the more restrictive standards or requirements of the State program. The more restrictive standards will not be used to restrict market access of organic product produced in other States or countries. Thus, there is no reason to receive public comment on requested State requirements from individuals not directly affected by the proposed requirements.

The commenter suggested that AMS also publish a summary of each proposed program and any amendments to a program in a newspaper of general circulation in the State. AMS will issue a public information notices which will announce each approved State organic certification program and any approved amendments of a State program. The notices will identify the unique characteristics of the approved State program that warranted the more restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP homepage.

(5) *State program consistencies.* Several commenters asked for clarification of the first proposal's terms, ''consistent'' and ''substantive amendments,'' used in regard to State programs operating under the NOP. Being ''consistent'' with the NOP means that a State program's written standards or requirements must be at least equal to the standards and requirements of the NOP. This is provided for in the Act. Further, in allowing State organic programs to have more restrictive or higher standards, the Act requires that those more restrictive standards and requirements be consistent with the purposes of the Act. To be ''consistent'' with the purposes of the Act means that the requested, more restrictive standards or requirements are of such a nature that they do not undermine the application of uniform national organic standards. Thus, if a request for more restrictive State organic standards is determined to not be consistent with uniform national organic standards, the State program will not be approved by the Secretary. The administrative procedures used by the State in administering the 11 general requirements of the State's organic program should have the same force and effect of the procedures use by AMS in administering this program.

The same commenters asked for clarification of the term, ''substantive amendments,'' in obtaining USDA approval of more strict amendments for one State's organic certification program. ''Substantive amendments'' means changes that would increase the quantitative or qualitative standards or specific requirements for an operation's or a product's certification under the State organic program. Once this national program is operating, if a question arises as to whether a desired change in a State organic certification program is considered substantive or not, the State program's governing State official should raise the issue with the Secretary.

State Programs—Additional Provisions

(1) *State program responsibilities.* This subpart establishes that a State organic certification program which petitions for approval by the Secretary will have increased responsibilities under the NOP. Our first proposal did not suggest qualifying factors or other information that had to be submitted by the State program's governing State official. This proposal specifies the 11 general requirements, addressed above, and the needs-based environmental

conditions or special production practices for establishing more restrictive requirements. Those factors establish our revised position that a State must agree to incurring increased responsibilities and obligations to be approved as a State organic certification program under the NOP. For instance, as discussed above, a State with an approved organic certification program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures in this proposal. Once approved by the Secretary, the State governing official or designee must effectively administer the State's organic certification program in a manner that is consistent and equitable for the certified parties involved in compliance actions.

A State's organic certification program may include other programs and projects which the State government may conduct to promote or increase organic production and handling in the State. Such programs may include organic promotion and research projects, transition assistance, a directory of organic production and handling operations in the State, a consumer referral program, or certifications given to retail operations which market organic foods. This proposal will not prohibit such State activities, provided those activities do not establish production or handling standards that work against the purposes of the NOP. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects should be beyond the scope of this national program and, if so, will not be subject to the Secretary's review.

(2) *Renewal of State program.* The final section provides that reviews of State organic certification programs will be conducted at least once every 5 years, as required in paragraph (c) of section 6507. The intent of the provision is not changed in this proposal. We will provide further information regarding reviews of State programs before the first 5-year period is completed. We expect that, with experiences gained from a few years of program operation, we will be able to propose more appropriate procedures, guidelines, and requirements to assure proper reviews of operating State organic programs.

Fees. This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the Department for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Proposal Description

Fees and Other Charges for Accreditation. Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization ''General Requirements for Bodies Operating Product Certification Systems'' (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of Subpart F, a nonrefundable fee of $500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters, or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by the Department, travel tolls, or, where the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing the travel charges will be prorated among all the applicants and certifying agents furnished the service involved on an equitable basis. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the Department. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include, but are not limited to, equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the Department. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

Payment of Fees and Other Charges. Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA–AMS–TMP–NOP,

Room 2945-South Building, PO Box 96456, Washington, DC 20090–6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

Fees and Other Charges for Certification. Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than $250.00 which must be applied to the applicant's fees-for-service account. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Based on Comments. This portion of subpart G differs from our first proposal in several respects as follows:

(1) *Application and Administrative Fees.* We have removed the provisions which required certifying agents to pay application and administrative fees. These fee provisions have been replaced with provisions for the assessment of fees for service equal as nearly as may be to the cost of the accreditation services rendered under these regulations. In other words, we will be assessing fees and charges only for activities related to accreditation. These fees and charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. The balance of costs incurred by the NOP will be funded through appropriations. We have retained the requirement, with modification, that certifying agents reimburse the Department for travel, per diem, and related other costs associated with providing accreditation services. We have taken these actions in an attempt to minimize the cost of this program on certifying agents. Certifying agents will be charged for the actual time and travel expenses necessary for the NOP to perform accreditation services.

This proposed program is similar to the Quality Systems Certification Program (QSCP) established pursuant to 7 CFR part 54. The QSCP is an audit-based program administered by AMS through its Livestock and Seed Program, which provides meatpackers, processors, producers, and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. Since the procedures used for accrediting State and private entities as accredited organic certifying agents are similar to those used to certify other types of product or system certification programs under the QSCP, we have decided to use this existing program and its staff in examining certifying agents' operations and evaluating their compliance with the Act and these regulations. Using the QSCP and its staff will enable the NOP to provide the necessary services without creating a separate bureaucracy. Hourly fees to be charged for services under this program will be the same as those under the QSCP, currently estimated at $95.00 per hour.

This fee of approximately $95.00 is greater than the $42.20 base rate charged under the voluntary user-fee-funded program established by AMS to verify that State and private organic certifying agents in the United States comply with the requirements prescribed under ISO Guide 65. This program, administered by the AMS Livestock and Seed Program, applied the aggregate meat grading rate for services to this ISO Guide 65 verification program for State and private organic certificating agents. The grading rate of $42.20 was the only rate for which AMS was authorized to charge at the time that the program to assess ISO Guide 65 conformity by organic certifying agents was implemented. This was not the actual audit rate of approximately $95.00 for such services. The AMS Livestock and Seed Program will engage in rulemaking to establish audit fees for its QSCP. As noted above, those fees are expected to be approximately $95.00 per hour. The NOP will notify accredited certifying agents of proposed rate changes and final actions on such rates by AMS.

To minimize the economic impact of implementing the NOP on certifying agents, we have decided to provide services for accreditation during the first 18 months following the effective date of new subpart F without an hourly charge for all applicants for initial accreditation and accredited certifying agents. This represents full subsidization of the hourly costs for accreditation by the Department during the first 18 months of operation. This 18-month subsidization of the hourly costs will prove especially beneficial to any applicant for accreditation that submits a substandard application or has difficulty establishing eligibility for accreditation. Certifying agents will be charged for accreditation service at the published hourly rate on the first day of the nineteenth month following the effective date of subpart F.

Over 15,000 comments were received on fees, with all opposing the first proposal's fee provisions. In addition to comments from consumers, comments were received from State agencies, organic growers, grower associations, and certifying agents. Most of these commenters expressed the belief that the proposed fees would price small certifying agents out of the organic industry. Almost half of the over 15,000 comments suggested a sliding-scale fee system, rather than the flat fee system in the first proposal, to accommodate the economic needs of small certifying agents. We have not accepted the concept of a sliding-scale fee system. Rather, as noted above, we are proposing that certifying agents be charged for the actual time and travel expenses necessary for the NOP to perform accreditation services. Under this fee system, smaller certifying agents should pay less in hourly charges to obtain and maintain certification than larger certifying agents. This assumption, however, is contingent on the quality of all documentation submitted to the Department, certifying agent recordkeeping, and the efficiency of the certifying agent in meeting the requirements of this part. The fees and other charges for accreditation regulations are found in § 205.640.

(2) *Payment by Certified Check.* We have removed the requirement that the payment of fees and charges to the Department be by certified check or money order. We have made this change because we agree with commenters that this requirement is unnecessary and potentially burdensome.

Nearly all industry commenters opposed the form and method of payments stated throughout the original fee sections. Commenters stated that payment by certified check or money order was unnecessary and would create an additional burden on individual producers, handlers, and private certifiers. A few State commenters stated that it was insulting for the U.S. Department of Agriculture (USDA) to require a State government agency to pay for its accreditation with a certified check.

(3) *Producer and Handler Fees to the Department.* We have removed the provisions which required the payment of certification fees by producers and handlers to the Department. We have taken this action because we believe that the goal of recovering program costs through fees and other costs charged to producers and handlers for certification as certified organic operations should be balanced against the Act's purpose to facilitate interstate commerce in fresh and processed food.

We received over 15,000 comments all opposing the first proposal's fee provisions for producers and handlers. Comments were received from consumers, State agencies, organic growers, grower associations, and certifying agents. Most of these commenters stated that the proposed fees would price small producers and handlers out of the organic industry. Hundreds of these commenters stated that the proposed fees favor large production operations. Almost half of the over 15,000 comments suggested a sliding-scale fee system, rather than the flat fee system proposed in the first proposal, to accommodate the economic needs of small producers and handlers. Hundreds more suggested that small producers and processors be exempt from the payment of fees.

Most of the State agency, organic grower, grower association, and certifying agent (industry) commenters spoke to the very small size and family-farm nature of the average organic production operation and how those operations would be affected by the proposed fees. Commenters from this group who offered estimates suggested that one-third to over one-half of organic producers in their area or State are very small organic producers operating at or near the exemption level of $5,000 in annual sales. They said those operating just above the exemption level could be forced out of organic production by the extra fee and the increased certification charges passed down by certifying agents who would have to pay the proposed accreditation charges.

Commenters, industry and consumer, stated that, rather than encouraging growth and new participation in organic agriculture, the costs of certification would stifle growth and discourage small producer participation in organic agriculture. An industry commenter stated that exempt producers who might want to be certified so they could market their product as organic would be dissuaded from doing so because of the cost of certification. Industry commenters also stated that the additional USDA fee on small handlers would make small organic handling operations marginal. A few State agencies commented that many small organic producers also conduct their own on-farm handling and that these operations would be forced out of the organic industry by the excessive handler fee and reporting burdens.

The comment, that exempt producers who might want to be certified so they could market their product as organic would be dissuaded from doing so because of the cost of certification, requires clarification. It may be true that such producers would be dissuaded from seeking certification because of the cost of certification. It is not true, however, that exempt producers must be certified to sell or label their production as organic. The Act exempts small producers, those who produce no more than $5,000 in agricultural products, from the requirement that a person may sell or label an agricultural product as organically produced only if such product is produced and handled in accordance with the Act.

Industry commenters recommended complete changes to the proposed fee structure. Most, like the consumer commenters, suggested a sliding scale for fees based on either size or sales volume. Several industry commenters stated that the Act does not require that USDA recover all program costs from assessments on producers, handlers, and certifying agents. They cited section 6522 of the Act as authorizing the use of appropriated funds to carry out the program. Some industry commenters suggested that appropriated funds should be used to cover all administrative and overhead costs and that fees collected from the industry should only be used for specific program activities such as accreditation. A few industry commenters suggested that organic farmers not be charged an AMS fee but that each be required to sign an affidavit of compliance with program requirements.

After further discussions within the Department and review of the comments, we have determined that the fee structure for the NOP should be modified to reduce costs to all organic sectors. We acknowledge that the fees proposed in the first proposal might have discouraged industry growth and might not have facilitated interstate commerce of organic products. Because we believe that fees and other costs charged to producers and handlers for certification as certified organic operations should be kept to a minimum to encourage industry participation and growth, we have removed the regulations which provided for the payment of fees to the Department by certified production and handling operations.

(4) *Estimated Cost of Certification.* We have added, at § 205.642, the requirement that the certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. Additionally, the certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule. We have added these provisions to ensure that producers and handlers have early and ready access to the information they need to consider cost in selecting an agent to certify their production or handling operation. We consider this to be especially important because, as noted in the preamble to subpart F, we have removed the requirement that the certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. We have removed this requirement because we concur with those commenters who expressed the belief that certifying agents should be permitted to set their own fees without the approval of the Secretary. We have also removed this requirement because we concur with the commenters' belief that production and handling operations are free to consider cost in selecting an agent to certify their production or handling operation.

Fees—Changes Requested But Not Made. This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Accreditation Charges Billed to State Certifying Agents.* Several State certifying agents stated that State certifying agents should not be assessed accreditation charges. Commenters stated that most State certifying agents could face large accreditation costs because they have many county or regional offices which would be considered subsidiaries of the headquarters office. They stated that these charges would have to be passed on to producers and handlers or paid with supplemental State funds. A few State certifying agents stated that USDA should pay the States, rather than vice versa, because of the State organic programs' contributions to the national program. At least one State representative commented that accreditation fees for State certifying agents should be less than for private certifying agents because State certifying agents should require less review and oversight by AMS.

We disagree with those commenters who recommended that State certifying agents not be assessed accreditation

charges, be charged less for accreditation, or be paid to certify production or handling operations. We view such actions as constituting unacceptable preferential treatment of State certifying agents to the detriment of private-entity certifying agents. Accordingly, under this proposal, State-entity certifying agents will be assessed fees for accreditation under the same fee structure as private-entity certifying agents.

(2) *Subsidization.* Some industry commenters stated that national governments in Europe provide direct subsidies and other economic incentives for their farmers to grow organic. A few questioned why the organic industry would be charged for services while some USDA programs are provided without cost to other agricultural sectors, and USDA actually pays some farmers not to grow some commodities. Industry commenters and many consumer commenters stated that it was unfair for this proposed program to charge all costs to a fledgling agricultural industry composed mostly of small, family farmers and marginal operations. Finally, a few industry commenters proposed the philosophical argument that program fees penalize those who protect the earth and that USDA should charge traditional producers who damage the earth with chemical applications and nonsustainable cultural practices.

AMS is primarily a user-fee-based Federal agency. The Act at section 6506(a)(10) requires the collection of fees from producers, handlers, and certifying agents. We are, therefore, unable to provide for the full subsidization of producers, handlers, and certifying agents as espoused by some commenters. Accordingly, this proposal provides for the payment of fees by producers, handlers, and certifying agents. We have, however, proposed regulations in this proposal which we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

Fees—Additional Provisions. Upon further review of the fee provisions in the first proposal, we have decided to propose the following additions.

(1) *Certification Fees Charged by Certifying Agents.* We have added, at § 205.642, regulations addressing general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. First, fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. This is a general requirement for accreditation and is also found at § 205.501(a)(15) in subpart F on accreditation. This regulation does not prohibit certifying agents from providing and charging for services outside the NOP. Services that certifying agents might provide outside the NOP include in-house publications, conferences, workshops, informational meetings, and field days. Certifying agents cannot require participation in such activities by certified operations or applicants for certification as a condition of certification.

Second, the certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than $250.00 which must be applied to the applicant's fees-for-service account. We believe that this fee will help ensure that certifying agents are compensated for certification services provided to an applicant that is found to be not qualified to receive certification as an organic production or handling operation.

(2) *Fees Charged to Foreign Certifying Agents.* We have removed the provisions which required the payment of fees for import programs. We have taken this action because this proposal includes foreign State entities and foreign private entities which provide certification services under the accreditation requirements of this part. Accordingly, such entities are covered under the fees for accreditation provisions of § 205.640.

Compliance

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the Secretary, USDA, and Agricultural Marketing Service (AMS) officials acting on behalf of the Secretary. These procedures also describe responsibilities of State programs' governing State officials (governing State officials) and State and private certifying agents for compliance under the NOP. The NOP is the AMS office that reviews applications and initiates approvals of accreditation of new certifying agents, conducts oversight of accredited certifying agents, and reviews and recommends continuation of accreditation of certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. Approval or denial of applications for certification and accreditation are addressed under subparts E and F, respectively.

Proposal Description

The Secretary is required under the Act to review the operations of State organic certification programs, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out oversight of compliance proceedings on behalf of the Secretary and the Administrator. However, most reviews and analyses of certification noncompliance will be conducted by the certifying agent which certified the operation. With regard to certifying agents, the Program Manager may initiate proceedings to suspend or revoke the accreditation of a certifying agent for failure to conduct accreditation activities or maintain accreditation requirements pursuant to subpart F of this regulation.

In States with an approved State organic certification program, the State program's governing State official is responsible for administration of the State's compliance program for certified operations. Governing State officials also may review and investigate complaints of certifying agents operating in the State who may not be in compliance with the accreditation requirements of the Act and these regulations. They must notify the Program Manager of such noncompliance activities and make information regarding the violation available to the NOP for appropriate action.

The Program Manager may initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or State program's governing State official fails to take appropriate enforcement action or if an operation is found to be erroneously certified by a certifying agent whose accreditation has been suspended or revoked.

The compliance provisions of the NOP are consistent with the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553–559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. An exception to the initial due process steps under the APA is provided in instances of willful violations. However, willful violations may be appealed pursuant to

the Appeals procedure in this subpart. A compliance action regarding certification carried out under an approved State program's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying applications for certification and applications for accreditation is laid out in subparts E and F respectively.

Noncompliance Procedure for Certified Operations. The Act provides for the enforcement of certified operations. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, residue and tissue testing, authority to conduct investigations, and responsibility to report violations. Applicants for certification must meet certification requirements of the NOP, as determined by certifying agents.

Notification of Noncompliance. As noted above, the Program Manager or the governing State official may review and investigate a certified operation based on complaints and may initiate noncompliance proceedings established in this subpart. However, we expect that most compliance procedures will begin with a certifying agent's inspection, review, or investigation of such certified operation. Thus, this noncompliance procedure is proposed based on that process.

A written notification of noncompliance will be sent to the certified operation if a certifying agent's inspection, review, or investigation reveals any noncompliance with the Act or these regulations. Noncompliance may include, among other things, production or handling practices or conditions, use of substances, or labeling which are not in compliance with subparts C, Production and Handling, or E, Certification, of this regulation. The results of a residue test may trigger a noncompliance notification. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation.

A notification of noncompliance will provide: (1) A description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and throughout the noncompliance proceeding and any appeal procedure which might follow the compliance proceeding.

All written notifications sent by certifying agents and governing State officials, as well as rebuttals, requests for mediation, and notices of correction of deficiencies sent by certified operations will be sent to the addressee's place of business by a delivery service which provides dated return receipts. This will help assure completed communications and timely compliance procedures.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the operation may submit a rebuttal to the certifying agent, providing supporting data to refute the facts stated in the notification. Rebuttals are provided to allow certifying agents and certified operations to informally resolve noncompliance notices. Rebuttals should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified deficiencies and submit proof of such corrections. When the operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent will send the certified operation a written notification of noncompliance resolution.

Proposed Suspension or Revocation of Certification. If the noncompliance is not resolved and is not in the process of being resolved by the date specified in the notification, the certifying agent will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) The reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation. A governing State official may not suspend or revoke certification of an entity's certified operations in other States. Likewise, a certifying agent may not suspend or revoke certification of an entity's operations which the certifying agent does not certify.

If a certifying agent determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal that suspension or revocation decision.

Mediation. A certified operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the noncompliance more quickly than the next step, which is filing an appeal. If a State program is in effect, the mediation procedures established in the State program, as approved by the Secretary, must be followed. Mediation will be requested in writing to the applicable certifying agent. The dispute will be mediated by a qualified mediator mutually agreed upon by the parties to the mediation. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the certified operation will have 30 days from termination of mediation to appeal the proposed suspension or revocation to the Administrator.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. Also, the Secretary reserves the right to review any mediated settlement to assure that the terms of the settlement conform with the requirements of the Act and the NOP.

Suspension or Revocation. The certifying agent will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance and on whether the noncompliance is a willful action by the certified operation. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or

otherwise violating the purposes of the Act. Certifying agents are responsible for investigating whether a violation is a willful act and advising the Program Manager or governing State official of the results of such investigation. However, only the Program Manager or governing State official may make the final determination that a violation is willful.

If a suspected willful noncompliance is not a serious violation, a proposed suspension rather than revocation may be issued. Revocation is reserved for serious instances of willful noncompliance and other serious violations.

The certifying agent may determine that a lesser penalty of suspension is warranted by the noncompliance. A proposal to suspend certification may be issued for violations that are inadvertent or cannot be proven to be willful. A suspension may be applicable only to one area of operation or one field or farm unit where the noncompliance occurred.

A certified operation that has had its certification revoked will not be eligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. If an individual is the owner of a certified operation or is the principal officer or director of operations who is fully responsible for complying with certification requirements of this part, a suspension or revocation could be issued in the individual's name. The effect would be that another operation would be ineligible for organic certification if that individual is listed as a principal in the operation. The Secretary may waive an ineligibility period when it is in the best interests of the certification program.

Noncompliance Procedure for Certifying Agents. The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who fails to carry out responsibilities entrusted to the certifying agent or maintain resources sufficient to meet accreditation requirements in subpart F. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, as a result of site visits, or as a result of investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of a governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut the noncompliance notice or correct each noncompliance described.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction of violations, the Program Manager will issue a proposed suspension or revocation of accreditation. The notification will state whether the certifying agent's entire business, field office, or offices in a geographic area or in a specified technical field of accreditation are to be suspended or revoked. For instance, if a private certifying agent with field offices in different geographic areas is cited for a compliance violation in one area, the Program Manager could determine that only the accreditation of the noncompliant operation should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification. The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager may issue a notification of proposed revocation of accreditation. The proposed revocation may be for the certifying agent's entire accreditation business, a particular field office, or a specified technical area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination, pursuant to § 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time submit a new request for accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

State Programs' Compliance Procedures. A State program's governing State official may initiate noncompliance proceedings of certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary. The governing State official must attempt to resolve the compliance violations through State mediation and reviews of corrections to operations.

The governing State official must promptly notify the Program Manager of commencement of enforcement proceedings initiated against certified operations. An enforcement proceeding, brought by a governing State official against a certified operation may be appealed in accordance with the appeal procedures of the State organic certification program. There will be no subsequent rights of appeal to the Secretary.

Compliance—Changes Based On Comments

This portion of subpart G differs from our first proposal in several respects as follows:

(1) *Authority of certifying agents.* We have provided accredited certifying

agents with authority to initiate noncompliance proceedings which may result in suspension or revocation of producer and handler certifications. A certifying agent's notification of proposed suspension or revocation of certification provides an opportunity for the certified operation to file an appeal in accordance with the appeal provisions of § 205.681. If a noncompliance procedure initiated by a certifying agent is not corrected, remains unresolved, and is not appealed, the certified operation's certification will be suspended or revoked. If the certified operation files an appeal, the action is turned over to the Program Manager or applicable governing State official for further resolution. The suspension or revocation will not become effective unless upheld by a ruling on the appeal.

Commenters expressed opposition to the notification of noncompliance with certification requirements and termination of certification provisions of the first proposal. Those provisions required a certifying agent to submit to the Administrator a notice of its recommendation to terminate the certification of a certified operation or any portion of a certified operation if the certifying agent had reason to believe the operation had ceased to comply with the Act and regulations. The commenters were opposed to the Secretary assuming authority for suspension or revocation of certification. The commenters stated that such decisions are the duty and responsibility of certifying agents, with the Secretary providing for appeals. Some commenters expressed the belief that the certifying agent's position is undermined by not having authority to suspend or revoke a certification for cause. Many commenters stated that certifying agents must have such authority in order to: (1) Achieve producer and handler compliance with the regulations; and (2) expedite the enforcement process. They believe that providing certifying agents with the authority to suspend or revoke a certification will preserve the NOP's integrity and increase consumer confidence in the quality of the organic products they purchase. Commenters stressed that, in addition to providing procedures for producer and handler appeals, the Department provides a system of checks and balances through the accreditation program.

We agree that certifying agents should have an important role to play in the suspension or revocation of the certification of production or handling operation that they certify. This proposal will enhance the certifying agent's authority to ensure that any production or handling operation it certifies is in compliance with the Act and regulations. We also agree that providing certifying agents with a more direct role in suspension or revocation proceedings will shorten the compliance process.

Accordingly, as noted above, we have provided accredited certifying agents with increased authorities in enforcement proceedings. They will make determinations to accept or reject rebuttals submitted in response to notifications of noncompliance. They will be responsible for defending their determinations, which must be consistent with the position of the NOP, in mediation processes. Finally, their decisions to propose suspension or revocation of producer and handler certifications will become effective unless appealed by the certified operation. Authority for certifying agents to take enforcement actions against certified operations is found in § 205.662.

(2) *Mediation.* We have added a new section authorizing certified operations to request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. This section addresses the request for mediation, selection of the mediator, the time period for reaching an agreement, requirements of an agreement, and appealing a noncompliance decision if mediation is unsuccessful. The parties in the procedure must make administrative arrangements for the mediation and arrange for payment of any costs involved in the mediation. The Department will not finance or participate in such mediation. This additional provision is found at § 205.663.

Commenters requested that the Department authorize the use of alternative dispute resolution procedures and mediation. We support the idea of using mediation to resolve disputes with respect to denial of certification or proposed suspension or revocation of certification. Some States use mediation as a component of their appeal process. We believe mediation could prove effective in resolving many of the possible disputes between applicants for certification or certified operations and certifying agents. Without mediation, such disputes would probably be referred to the Administrator in the form of appeals. Mediation in some cases, however, may be of limited value because all agreements reached during mediation or as a result of the mediation process must be in compliance with the Act, these regulations, and any policies or procedures governing the NOP. While we presume a mediated settlement will be in accordance with the Act, the Secretary has authority to review and overrule a mediated settlement if the Secretary determines the settlement is not in accordance with Act and these regulations.

(3) *State certification program.* Commenters generally requested that States administer and enforce their own organic certification programs. We have added regulations in these provisions addressing States' enforcement of their programs regarding certified producers and handlers operating in the State. These regulations clarify a State's responsibility to provide for enforcement and appeal proceedings which are consistent with these regulations and for keeping the Secretary informed of such proceedings. We have added these regulations because we believe that a State must have the authority to initiate compliance actions to enforce its organic certification program. The regulations are found at § 205.668.

Regarding accreditation authorities, commenters stated that a State program's governing State official should have authority to suspend or revoke the accreditation of private certifying agents operating within the State. Sections 6515(j) and 6519(e) of the Act address suspension and revocation of accreditation by the Secretary or governing State official. While the Act may provide for the possibility of such authority being used by governing State officials, it also requires the Secretary to establish a workable accreditation program and it grants sole authority to the Secretary to accredit certifying agents. Therefore, the Secretary must have sole authority to suspend or revoke that accreditation.

This does not mean that governing State officials are denied a role in oversight of certifying agents operating in their States. If a governing State official believes a certifying agent operating in the State is not in compliance with the accreditation requirements of the Act or is not properly certifying producers or handlers to NOP and the State's approved unique organic certification requirements, the governing State official must investigate the possible noncompliance. If evidence of noncompliance is found, the governing State official must notify the Program Manager of such noncompliance activities and document those activities. The Program Manager will investigate such complaints of noncompliance.

(4) *Right of appeal.* We have added the requirement that any notification of proposed suspension or revocation must include a notice to the certified operation's or certifying agent's of its right to file an appeal. Commenters requested that the notification of proposed suspension or revocation provisions for certifying agents reference the appeals section. We agree with the commenters' request and add that all recipients of a notification of proposed suspension or revocation should be made aware of their appeal rights. Notification of appeal rights is found in § 205.662 for certified operations and § 205.665 for certifying agents.

Compliance—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Revocation period.* Commenters stated that a 5-year period of ineligibility for certification after revocation of certification is too harsh a punishment to apply in all cases. Some commenters suggested that ''shall not be eligible'' should be replaced with ''may be deemed ineligible'' so that the penalty provision would be available for flagrant violations of the Act but would not have to be applied to all violations. A commenter suggested a maximum period of ineligibility of 3 years be established for certified operations. The commenter's justification was that organically produced agricultural products must be produced on land to which no prohibited substances have been applied for 3 years prior to harvest. This commenter also stated that the ineligibility waiver should be a local decision with notice to the Administrator.

Section 6519(c) of the Act requires certification ineligibility for 5 years unless reduced or eliminated by the Secretary. Revocation of a certification is a serious action subject to due process for the accused certified producer or handler. We believe that any noncompliance action, combination of noncompliance actions, or history of noncompliance activities deemed to warrant the revocation of certification also warrants ineligibility from certification for 5 years unless reduced or eliminated by the Secretary. If the noncompliance is not significant enough to warrant revocation of the operation's certification, the certifying agent, State program's governing State official, or Secretary may choose to suspend the operation's certification for a period of time less than the 5-year revocation period. We disagree with the suggestion that ineligibility waivers should be decided at the local level. Actions which are finalized by the governing State official, Administrator, or Secretary cannot be subject to reversal or waivers by certifying agents. Additionally, a national program such as this must have uniformity in application, which would be less likely if individual certifying agents were permitted to establish their own criteria for ineligibility waivers. Accordingly, the ineligibility and waiver provisions are unchanged in this proposal.

(2) *Accreditation sanctions.* Commenters stated that suspension and revocation of accreditation should be applied fairly to both private and State certifying agents. Governing State officials do not have any accreditation authorities under this proposal—which may reduce private certifying agents' concerns of unfair or unequal treatment. Accreditation compliance actions by the Program Manager and the Administrator will be conducted impartially and in accordance with the Administrative Procedure Act and Department policies.

Revocation would be based on a determination that a private certifying agent willfully violated the Act or these regulations or falsely or negligently certified a production or handling operation as an organic operation. The Act does not authorize the revocation of a State certifying agent's accreditation. However, because suspension of such entity can be established for any period of time, a suspension can be effectively equivalent to a revocation of accreditation. Accordingly, this proposal retains the provisions for the suspension of accreditation for private and State certifying agents and the revocation of accreditation for private certifying agents.

Compliance—Additional Provisions

Upon further review of the accreditation provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Enforcement rights of the Secretary.* We have added a general section addressing specific enforcement rights of the Secretary. First, this section clarifies that the Program Manager on behalf of the Secretary and the Administrator may inspect and review State organic certification programs, accredited certifying agents, and certified production or handling operations for compliance with the Act or regulations. The Program Manager has this oversight authority in States with State organic certification programs as well as in States without such programs.

Second, this section provides that the Program Manager may initiate proceedings to suspend or revoke a certified operation's certification when a certifying agent or governing State official fails to take appropriate enforcement action against a certified operation that is not in compliance with the Act or these regulations. We have added this provision because this proposal provides certifying agents and governing State officials with enforcement authorities, including the suspension and revocation of certifications. However, we believe the Secretary, through the Program Manager, must have authority to take such actions if a certifying agent or governing State official fails to carry out its responsibilities.

Third, this section provides that the Program Manager may initiate proceedings to suspend or revoke a certified operation's certification upon suspension or revocation of the operation's certifying agent's accreditation. We have added this provision to enable the Program Manager to suspend or revoke certification of any operation that a certifying agent certified following procedures or practices that are not in compliance with the Act or these regulations. This addition is found at § 205.660.

(2) *Certifying agent investigations.* We have added a section to clarify that certifying agents may investigate complaints of noncompliance with the Act or regulations concerning operations that they have certified. This section does not authorize a certifying agent to investigate certified operations that the certifying agent has not certified. Such complaints should be reported to the certifying agent that certifies the operation in question. This addition is found at § 205.661.

(3) *Certified operation rebuttals.* We have added a certified operation's right to rebut any noncompliance described in a notice of noncompliance. We believe this provision is necessary to clarify that certified operations should be able to present facts or arguments refuting the certifying agent's findings. We see this as an informal process between the certified operation and the certifying agent to clarify possible misunderstandings or misinterpretation of requirements, data, or information. The APA requires such opportunities prior to suspension or revocation. Certified operations that successfully refute a finding of noncompliance will receive a notification of noncompliance resolution. Any certified operation unable to successfully refute a finding of noncompliance must correct the

noncompliance or face possible suspension or revocation of its certification. This addition is found at § 205.662(a)(3).

(4) *Certifying agent rebuttals.* We also have added a certifying agent's right to rebut any accreditation noncompliance described in a notice of noncompliance issued by the Program Manager. This also will be an informal process and is consistent with the intent of the APA. We believe this provision is necessary to clarify that certifying agents should be able to present facts or arguments refuting the Program Manager's findings. Certifying agents that successfully refute a finding of noncompliance will receive a notification of noncompliance resolution. Any certifying agent unable to successfully refute a finding of noncompliance must correct the noncompliance or face possible suspension or revocation of its accreditation. This addition is found at § 205.665(a)(3).

(5) *Willful noncompliance.* We have also added authority for certifying agents and governing State officials to move directly to a notice of proposed revocation if a certification noncompliance is a willful, serious violation of these regulations. This will allow expedited action in dealing with serious violations of certification. The due process provisions of the APA provide an exception in cases of willful violations. Even though a noncompliance may be a willful act, the certified operation maintains the right to file an appeal of a proposed suspension or revocation of certification. Revocation of certification is reserved for serious instances of willful noncompliance and other serious violations. If a suspected willful violation is deemed not serious, a proposed suspension of certification rather than revocation may be issued.

Inspection and Testing, Reporting, and Exclusion From Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Based on comments received regarding the first proposal, we have modified and restructured our residue testing requirements. Commenters were concerned about the cost of residue testing to certified operations and certifying agents, the determination of detectable levels of prohibited substances, and the exclusion of contaminated products from sale as organically produced.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State programs' governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) Preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Proposal Description

Under the residue testing requirements of the NOP, we propose that all agricultural products sold, labeled, or represented as organically produced be available for inspection by the Administrator, State program's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under proposed Subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the State program's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances. *The cost of such testing will be borne by the applicable certifying party and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.*

Preharvest and Postharvest Residue Testing. The main objectives of the residue testing program are to: (1) Ensure that certified organic production and handling operations are in compliance with the requirements set forth in this proposal; and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance found in or on samples during chemical analysis will serve as a warning indicator to the State program's governing State official or certifying agent.

The request for preharvest or postharvest residue testing is based on the Administrator's, State program's governing State official's, or certifying agent's belief that an agricultural product has come into contact with one or more prohibited substances. The ''reason to believe'' could be triggered by various situations, for example: (1) The applicable authority receiving formal written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) when the product from a certified organic operation is unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, certifying agent, or State program's governing State official will conduct sampling. Testing for chemical residues must be performed in an accredited laboratory, defined as a laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) (FACT Act) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide analysis of products derived from livestock and fowl. AMS is currently developing a regulation for the National Laboratory Accreditation Program (NLAP), which will accredit laboratories under the FACT Act. We expect that the NLAP will be implemented before or at the same time as the NOP. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the 16th edition of the *Official Methods of Analysis of the AOAC International* or other applicable validated methodology for determining the presence of contaminants in agricultural products.

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with a national mean of detection for the specific commodity/pesticide combination generated by the U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP). This national mean is defined as the mean level of detected pesticide residues as described in certain pesticide/commodity pairs or combinations established by USDA's Pesticide Data Program. The national mean for specific commodity/pesticide combinations will serve as a standard for the Administrator, State programs' governing State officials, and certifying

agents to assist in monitoring for illegal use violations. This information will be made available by USDA to aid State programs' governing State officials and certifying agents in making sound evaluations and decisions regarding detected levels of prohibited substances.

In addition, levels of unavoidable residual environmental contamination will be determined for crop-and site-specific agricultural commodities to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).'' These levels will represent limits at which the Department may take compliance action to suspend the use of the contaminated area for organic agricultural production. Initially, unavoidable residual environmental contamination levels will be set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. In time, they may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable. Historical residue data gathered from Federal and State monitoring and testing programs will be used to determine these levels. They will be set by the Administrator, in consultation with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA).

After all tests and analyses have been concluded, the results must be provided to the Administrator. The results of analyses and tests will be available, kept on record, and reviewed by the Department to evaluate concentration levels of prohibited substances for specific regions and agricultural crops. Analyses and test results will also be available for public access, unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances. In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients),'' detectable residues of prohibited substances that exceed the national mean of detection for the respective commodity/pesticide combination or unavoidable residual contamination levels cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in §§ 205.662 and 205.663 of Subpart G, Compliance. In addition, when a State program's governing State official or a certifying agent detects a prohibited substance in or on agricultural products to be sold or labeled as organically produced, the State program's governing State official or certifying agent may conduct an investigation to determine the cause of the prohibited substance.

If the investigation into the cause of a detectable residue level in a product indicates that the residue was the result of an intentional application of a prohibited substance, the Administrator is authorized to initiate proceedings to revoke or suspend the certification status of an operation or portion of that operation. When testing indicates that an agricultural product contains prohibited substances that exceed either the EPA tolerance level or FDA action level, as applicable, for the prohibited substance, the data revealing such information will be promptly reported to the appropriate regulatory health agencies.

Emergency Pest Eradication or Disease Treatment Programs. When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest eradication or disease treatment program and the organic handling or production operation otherwise meets the requirements of this proposal, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, provided that: (1) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest eradication or disease treatment program cannot be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'; and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).''

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Residue Testing—Changes Based on Comments

This portion of subpart G differs from our first proposal in several respects as follows:

Residue Testing. (1) We have revised the first proposal's section on residue testing and repositioned it under § 205.670(b).

Commenters disagreed with the provisions in the first proposal which required certifying agents to conduct residue testing of products produced and handled on operations that they had certified not less frequently than every 5 years. They stated that the first proposal's requirements for residue testing: (1) Were in excess of what the Act actually requires; (2) were more stringent than that of the industry norm; (3) would create an unnecessary burden on certifying agents and organic production and handling operations; and (4) would increase costs for certified production and handling operations. The commenters stated that the NOP's residue testing requirements should utilize existing Federal and State testing programs for the detection of pesticide residues. They also stated that residue testing should only be required when it is known or suspected that prohibited substances have been applied to organic products.

We disagree with the commenters' assertions regarding the first proposal's requirements for residue testing. However, in an attempt to minimize the burdens of residue testing, we have proposed that State programs' governing State officials and certifying agents may test agricultural inputs used for organic production and require preharvest or postharvest testing of any agricultural product to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' when there is reason to believe that the agricultural product has come into contact with prohibited substances. This change allows State programs' governing State officials and certifying agents to perform preharvest and postharvest residue testing on a case-by-case basis.

Commenters requested that the rule specify which laboratories are authorized to perform residue testing and what tests each laboratory would be accredited to perform. We have defined

an accredited laboratory as a laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide residue analysis of products derived from livestock and fowl. Any laboratory that meets the specified requirements therein may be used in conducting residue tests. We have required that accredited laboratories be used to ensure consistency among data, testing methodology, reporting procedures, and other testing criteria needed to maintain analytical uniformity in the residue testing program. Validated analytical methodologies for determining the presence of contaminants in agricultural products, such as those described in the 16th edition of the *Official Methods of Analysis of the AOAC International,* may be used.

Tolerance Levels for Pesticide Residues. (2) We have prohibited the sale and labeling of agricultural products as organic when such products have been tested for prohibited substances and found to contain residues of prohibited substances at levels greater than the national mean of detection for the specific commodity/pesticide combination or levels greater than the unavoidable residual environmental contamination. Such agricultural products cannot be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).'' The Administrator, State program's governing State official, or certifying agent may conduct an investigation of the applicable production or handling operation to determine the cause of the presence of any prohibited substance. If the investigation reveals that the presence of a prohibited substance was the result of intentional application of the prohibited substance, the Administrator may initiate proceedings to suspend or revoke the production or handling operation's certification.

(3) Commenters suggested that USDA adopt a uniform standard for the maximum allowable residue levels. Some commenters expressed the belief that it is impractical or too expensive to establish site-specific, unavoidable residual environmental contamination levels for every commodity/pesticide combination in every growing area. Others argued that the cause of contamination is irrelevant and that crops that exceed the maximum residue levels should not be allowed to be sold as organic. Finally, others argued that a single standard was needed because contaminated products would not be removed from the market immediately, pending determination of cause.

Organic standards, including provisions governing prohibited substances, are based on the method of production, not the content. The primary purpose of the residue testing approaches described in this proposal, then, is to provide an additional tool for State programs' governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP. We acknowledge that consumers have a reasonable expectation that organic products will contain minimal residues of prohibited substances. We are not allowing the use of prohibited substances. We are making provisions for the unavoidable occurrences of prohibited substances while ensuring that residue levels are consistent with consumer expectations.

This proposal adopts PDP's national means of detected residue for specific commodity/pesticide combinations and the unavoidable residual environmental contamination levels. Both standards have been adopted for the purpose of determining excessive prohibited substances on agricultural products to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).''

The national mean of detected residue for a specific commodity/pesticide combination is derived from detections in the PDP monitoring program. As a result of mean values being based on conventional substances, we believe that residue values that fall above this mean, then, would be beyond reasonable consumer expectations for minimal residues. The situation is very similar with respect to unavoidable residual environmental contamination levels. Even though the presence of residues of certain persistent substances may not be the result of intentional application, we believe that excessive residue levels would not be consistent with the intentions of the Act. Accordingly, when levels of a persistent substance are detected above the unavoidable residual environmental contamination level, the product cannot be sold or labeled as organically produced.

Some commenters suggested that we use a percentage of the EPA tolerance of FDA action level, such as 5 or 10 percent, as a uniform standard for the maximum allowable residue level. We considered the comments but decided not to adopt them for the following reasons. The EPA tolerances for pesticides are defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity, as set by the Environmental Protection Agency under the Federal Food Drug and Cosmetic Act, section 408. FDA action levels represent limits, at or above which FDA will take legal action against a food product to prevent poisonous or deleterious substances from entering the food supply. Both EPA tolerances and FDA action levels are public health-based standards. Our rationale for residue testing, as a tool for State programs' governing State officials and certifying agents to monitor compliance with the NOP, is different from these public health programs.

Accepting a percentage of EPA tolerance or FDA action levels could also pose a significant problem for analytical laboratories trying to analyze for prohibited substances. In some cases, pesticides have tolerances that are set near their analytical method's Limit of Quantification (LOQ). The LOQ is defined as the lowest level where analytical measurement becomes quantitatively meaningful. If the EPA tolerances are near the analytical method LOQ's, accurate determination of the levels at 5 to 10 percent of the tolerance may not be attainable for analytical instrumentation currently employed. Therefore, the Department could be setting a level of concern below the LOQ for some substances if it adopted this recommendation. As a fundamental principle, we have chosen not to set an enforcement level that could be below detection limits for some substances. As an alternative, we are proposing to use the PDP national mean of detected residues for specific commodity/pesticide combinations.

Other commenters suggested that USDA adopt a ''zero tolerance'' for residues of prohibited substances. Under this suggestion, products containing any detectable residues of a prohibited substance would not be allowed to be labeled as organically produced. This proposal does not adopt this suggestion. While standards strictly prohibit use of any substance not found on the approved National List, we recognize that some minimal residues may still be found in organic foods. We believe our proposed residue testing system and compliance provisions should be adequate to protect the integrity of agricultural products sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).''

Several commenters expressed opposition to the first proposal not requiring residue testing in the event of drift. These commenters stated that organic producers should report all incidences of drift to their certifying agent. The commenters further stated that a crop should be tested for the

presence of prohibited substances when drift has or is suspected to have occurred. They also stated that when the test indicates levels of residues of prohibited substances that exceed 5 percent of the EPA tolerance level, the crop should be prohibited from being sold or labeled as organically produced.

In response to commenters' concern about contamination from drift, we have used some of their reasoning in the development of our residue testing program. Drift is defined as the physical movement of prohibited substances from the intended target site onto an organic production operation or any portion thereof. The National Organic Standards Board (NOSB or Board) recommended that agricultural products exposed to drift not be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' or fed to livestock on organic operations. The NOSB also recommended that preharvest tissue testing of crops suspected of receiving drift be required to verify the presence or absence of prohibited substances. This proposal addresses the problem of drift through the use of preharvest testing of crops suspected of receiving drift of a prohibited substance. Although drift may occur, especially in those agricultural regions where pesticide use on nonorganic lands is routine and heavy, exposure to drift does not constitute use of a prohibited substance. Therefore, preharvest testing provisions have been established for State programs' governing State officials and certifying agents to test when there is a reason to believe that agricultural products intended to be sold or labeled as organically produced have come into contact with prohibited substances. This will allow a State program's governing State official or certifying agent to determine whether the integrity of the product has been affected. We believe our proposed residue testing program and compliance provisions should be adequate to protect the integrity of agricultural products.

Residue Testing—Changes Requested but Not Made

(1) The original proposal provided that land subject to a Federal or State emergency disease or pest treatment program should not lose its organic certification and should not be required to be withheld from organic production for a period of 3 years. A few commenters stated that a field treated under such emergency situations should lose its certification and should be restricted for organic use for 3 years following the emergency treatment. The commenters stated this is necessary to maintain consumer confidence in organically produced products. We believe the first proposal is consistent with the requirements of the Act. The proposal provided that crops and livestock that had contact or been treated with a prohibited substance under such an official emergency treatment program could not be sold or labeled as organic. This proposal retains that prohibition.

Commenters suggested that producers work with the Federal or State agency which requires an emergency treatment program and arrange for use of materials that are compatible with organic production. While this may be possible under certain emergency treatment situations, it cannot be relied on as a solution to every emergency treatment situation. Appropriate alternative treatments may not be available, or the jurisdiction requiring the emergency program may not grant alternative treatments. Commenters also suggested that producers avoid planting crops that might be subject to pests or diseases targeted by emergency treatment programs to avoid emergency treatments. We do not believe that is a reasonable solution for producers. Emergency treatment programs are used in response to unforeseen infestations and diseases. Only hindsight would help organic producers determine which crops to produce. Further, the possibilities of damaging insect infestations or plant or animal diseases warranting an emergency treatment program are so numerous that an organic producer could be left with few or no alternative crops or livestock to produce. Cultural conditions and market factors also would limit selection of alternative organic production. Accordingly, the commenters' recommendation that loss of organic certification and an automatic 3-year prohibition on organic production from land or livestock treated under an official emergency treatment program is not accepted.

Residue Testing. (2) Commenters suggested that some of the responsibility of residue testing be removed from certifying agent responsibilities. They also suggested that residue testing requirements take into account current Federal and State testing requirements already in place for the detection of pesticide residues.

We have not adopted language that the Department would use current Federal and State testing requirements for the detection of pesticide residues in the residue testing program. Although State and Federal testing provide good sources of data on pesticide residues, the data may reflect criteria developed for different sampling purposes, showing wide variations in sample selection and indicating different laboratory capabilities and different levels of quantification between and within laboratories.

Residue Testing—Additional Provisions

Section 205.670(a) has been added. It provides that the Administrator, the State program's governing State official, and the applicable certifying agent have access, for inspection purposes, to all agricultural products being sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).'' In addition, the organic products must be made available for examination by said authorities in the manner that they prescribe.

Public comments did not suggest this action. However, we believe it is necessary to officially grant the Administrator, the State program's governing State official, and the applicable certifying agent the authority to access all agricultural products subject to inspection under this section. This authority will help resolve conflicts that may arise regarding product accessibility during inspection and testing.

Adverse Action Appeal Process. This portion of subpart G sets forth the general framework for an appeal process for persons subject to compliance determinations under the National Organic Program (NOP). In this proposal, we are empowering certifying agents with the authority to make decisions concerning denial of certification and the suspension or revocation of certified operations. This empowerment of certifying agents makes the appeal process very important.

We envision two kinds of appeals will be filed under these procedures: (1) Producers and handlers appealing denial of certification and proposed suspension and revocation of certification decisions by certifying agents; and (2) certifying agents appealing denial of accreditation and proposed suspension and revocation decisions by the NOP Program Manager. The Administrative Procedure Act (APA) (5 U.S.C. 553–559) provides that entities such as certified operations and accredited certifying agents have the right to appeal any adverse actions taken against their certification or accreditation, respectively. Applicants for certification and applicants for accreditation who receive a denial of certification or accreditation may appeal that denial following this appeal

procedure. The appeal process is the same for applicants as for certified operations and accredited certifying agents.

The informal appeal process described in this section is an extension of the noncompliance proceeding outlined in the Compliance section of this subpart.

For certification proceedings, the NOP and the Administrator will oversee compliance proceedings and handle certification appeals from operations in States that do not have an approved State organic certification program. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Secretary will initiate a formal administrative review process, which includes a hearing before an administrative law judge and review by the Department's Judicial Officer. The formal administrative review process will be conducted pursuant to the Department's Uniform Rules of Practice, 7 CFR 1.130 through 1.151. The formal administrative review will be the Department's final determination on the noncompliance proceeding. That decision may be appealed to the District Courts. This section addresses the informal appeal process which is used to arrive at the Administrator's decision to sustain or deny an appeal.

In States with approved State organic certification programs, the governing State official or designee will oversee certification compliance proceedings and handle appeals from certified operations in the State. The governing State official or designated appeals official will rule on appeals filed under a State organic certification program. Further appeal of that decision may be made to the district court system.

Proposal Description

These appeal procedures provide that persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent, Program Manager, or governing State official may appeal such decision to the Administrator or to the applicable State's appeal process. Under Compliance provision in this subpart, accredited certifying agents initiate noncompliance proceedings. If an appeal of a certification decision is filed, the process is referred to the Administrator or governing State official or designee, as applicable, to the State where the applicant or certified operation resides.

Certification Appeals

Applicants for certification may appeal a certifying agent's denial of certification. Certified operations may appeal a certifying agent's notification of proposed suspension or revocation of the operation's certification. These appeals will be made to the Administrator or to the applicable governing State official or designated official in the approved State organic certification program.

Certification appeals may be filed only after an applicant or a certified operation has been given opportunity to come into compliance with these regulations or otherwise resolve the specified noncompliance. Prior to filing an appeal, the applicant or certified operation must have failed in rebuttal, refused to make specified corrections, or made corrections which the certifying agent subsequently determined to not meet certification requirements of the NOP.

If the Administrator or governing State official sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The applicant or certified operation will not be required to correct the actions or conditions cited in the noncompliance notification. The act of sustaining the appeal will not be considered an adverse action and may not be appealed by the certifying agent which issued the notification.

If the Administrator or governing State official denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted pursuant to the Department's Uniform Rules of Practice or pursuant to the State's formal appeal procedures. Certified operations may continue to operate throughout this informal appeals process and the formal administrative proceedings.

Accreditation Appeals

Pursuant to § 205.665 of this subpart, all accredited certifying agents are subject to the Program Manager's review of their operations and any noncompliance actions resulting from such reviews. As provided in § 205.668, a State program's governing State official must advise the Program Manager if an investigation of a certifying agent reveals that the certifying agent is not in compliance with the Act or these regulations. The appeal process for applicants is the same as for accredited certifying agents.

An appeal may be filed with the Administrator only after the certifying agent fails to rebut the noncompliance notice and fails to correct the noncompliance specified. If the Administrator sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The applicant or certified operation will not be required to correct the actions or conditions cited in the compliance notification. If the appeal is denied, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation.

The certifying agent may continue to operate as a certifying agent throughout the informal appeals process and the formal administrative proceeding.

All appeals to the Administrator must be filed in writing and sent to: Administrator, USDA–AMS, Room 3071–S, PO Box 96456, Washington, DC 20090–6456. An appeal must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper and not made in accordance with applicable program regulations, policies, or procedures. A certified operation must send a copy of its appeal, to its certifying agent. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Appeals under a State's procedure will be filed pursuant to the State's appeal process, which should include addresses and filing periods, etc.

An appeal must be filed within the time provided in the letter of notification or at least 30 days from the date of receipt of the notice to deny, suspend, or revoke certification or accreditation. The appeal will be considered ''filed'' on the date received by the Administrator or, when applicable, the State program's governing State official or such official's designee. The Administrator will notify the appellant and the appellant's certifying agent that the appeal was received. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or an accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

Appeals—Changes Based On Comments

These appeal regulations differ from our first proposal as follows:

(1) *Decision-making.* We have clarified who will be making decisions that may be appealed to the Administrator. This proposal provides that persons subject to the Act who, during noncompliance proceedings described in this subpart, believe that

they are adversely affected by a noncompliance decision of a certifying agent, Program Manager, or governing State official may appeal such decision to the Administrator or the State's designated appeals official. This clarification is found in § 205.680.

Commenters stated that the proposed appeals procedures limited appeals to decisions of the NOP staff. Commenters requested that the appeals procedures be available for decisions by the Secretary, any representative of the Secretary, and decisions by any certifying agent. What we meant in the first proposal was that appeals would be filed on decisions made by the Program Manager and certifying agents.

As noted above, we are empowering certifying agents to make decisions concerning denials of certification and suspension or revocation of certified operations' certifications. Certifying agents accredited under this program act on behalf of the Secretary and the Administrator to carry out certification services, including noncompliance actions. The Administrator or designated governing State official will make decisions to either sustain or deny appeals by certification applicants and certified operations, as applicable to the State.

The Program Manager will make decisions to deny applications for accreditation and to suspend or revoke certifying agents' accreditations. The Administrator will make all decisions to either sustain or deny appeals by accreditation applicants and certifying agents.

(2) *Appeal procedures.* Commenters requested detailed appeal procedures or the use of citations to identify existing Departmental appeal procedures which would be used for appeals filed under this program. We acknowledge that the first proposal lacked detailed appeals provisions. However, we believe this explanation is more informative and helpful for the commenters. The formal administrative procedure following the Department's Uniform Rules of Practice is required under the APA. The rules of practice are not included in individual rulemaking actions but may be found under 7 CFR 1.130 through 1.151. The combination of this informal appeal procedure followed by the formal administrative proceeding assures applicants, certified operations, and accredited certifying agents that they will be given full opportunity to respond to any noncompliance proceeding brought against their application or operation. Individual State programs will have their own, approved appeal procedures.

Commenters also recommended that the Department should use an independent USDA appeals division to avoid conflict of interest by the Program Manager or the Administrator in the handling of appeals. We believe this proposed appeal procedure ensures that appeals will be administered by persons not involved in the decision being appealed. This appeals procedure is consistent with the requirements of the APA.

Paragraph (a)(1) of § 205.681 provides that if the Administrator sustains an applicant's or certified operation's appeal of a certifying agent's noncompliance decision, the act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent. We have included this provision because, as noted above, certifying agents are accredited by the Secretary to provide certification services as agents of the Secretary and the Administrator. Therefore, if the Administrator overrules a decision of an accredited certifying agent, that certifying agent cannot request an appeal of the Administrator's decision.

Appeals—Changes Requested But Not Made

None.

Appeals—Additional Provisions

(1) *State appeals procedures.* We are proposing that appeal proceedings in States with organic certification programs approved by the Secretary will be carried out in accordance with the official administrative appeal proceedings in each State. A State's appeal process will be included as part of the State's organic certification program. Because a State's appeal procedure is approved by the Secretary, the final determination for a certification appeal arrived at under that procedure is considered to have the effect of a decision by the Secretary. Approved State appeal processes are unique to each State and are not included in this regulation.

Certification appeals are made to the State program's governing State official or such official's designee. The governing State official or designee will administer the appeal pursuant to appeal procedures which have been approved by the Secretary. Rulings on such appeals, as noted in § 205.668, may not be appealed to the Secretary. The certification applicant or certified operation may make subsequent appeal to the Court of Appeals of the United States for the circuit in which such applicant or certified operation carries on business or in the United States Court of Appeals for the District of Columbia Circuit.

(2) *Accreditation appeals.* This proposal provides that the Program Manager carries out all compliance proceedings on accredited certifying agents. The Secretary has sole authority for accrediting certifying agents and, therefore, must retain sole authority for suspending or revoking that accreditation. A State program's governing State official must investigate any complaints of noncompliance on the part of a certifying agent operating in the State. If noncompliance activities or conditions are found, the governing State official must notify the Program Manager of those compliance violations or suspected compliance violations.

Miscellaneous

Section 205.690 provisions the Office of Management and Budget control number assigned to the information collection requirements of these regulations. Sections 205.691 through 205.699 are reserved.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Foods, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, it is proposed that Title 7, Chapter I of the Code of Federal Regulations be amended as follows:

1. Parts 205 through 209 which are currently reserved in subchapter K (Federal Seed Act), are removed.

2. A new subchapter M consisting of part 205 through 209 is added to read as follows:

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

Sec.

Subpart B—Applicability

Subpart C—Organic Crop, Wild Crop, Livestock, and Handling Requirements

Authority: 7 U.S.C. 6501–6522.

Subpart A—Definitions

205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

205.2 Terms defined.

Accredited laboratory. A laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide residue analysis of products derived from livestock and fowl.

Accreditation. A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*).

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

Administrator. The Administrator for the Agricultural Marketing Service (AMS), United States Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production, or handling.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operation. The types of operations: Crops, livestock, wild-crop harvesting, handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as ''100 percent organic,'' the organic ingredients of any agricultural product labeled as ''organic'' or ''made with organic (specified ingredients)'' or the organic ingredients of any agricultural product containing less than 50 percent organic ingredients identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

Buffer zone. An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting, or handling operation or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

Certifying agent's operation. All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients),'' or, in the case of agricultural products containing less than 50 percent organic ingredients, the term, ''organic,'' on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Commingling. Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

Compost. The product of a carefully managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost used in an organic operation must be produced in a facility in compliance with the Natural Resource Conservation Service's practice standard for a composting facility (Code 317) and must use methods to raise the temperature of the raw materials to the levels needed to stabilize nutrients and kill pathogens.

Control. Any method that reduces or limits damage by populations of pests, weeds, or diseases to levels that do not significantly reduce productivity.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Crop residues. The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years, so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop sequencing.

Crop year. That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

Cultural methods. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by the current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

Emergency pest or disease treatment program. A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person providing paid or volunteer services for a certifying agent.

Estimated National Mean. The mean level of detected pesticide residues as described in certain pesticide/commodity pairs or combinations established by USDA's Pesticide Data Program.